Regulations Governing
the Classification of Medical Devices (Draft)

Article 1 These Regulations are enacted pursuant to Paragraph 2, Article 3 of the Medical Devices Act (hereinafter "this Act").

Article 2 Medical devices are classified into the following categories according to their function, intended use, operating instructions, and working principle, depending on the applicable medical specialty:

1. Clinical chemistry and clinical toxicology devices
2. Hematology and pathology devices
3. Immunology and microbiology devices
4. Anesthesiology devices
5. Cardiovascular devices
6. Dental devices
7. Ear, nose, and throat devices
8. Gastroenterology and urology devices
9. General and plastic surgery devices
10. General hospital and personal use devices
11. Neurological devices
12. Obstetrical and gynecological devices
13. Ophthalmic devices
14. Orthopedic devices
15. Physical medicine devices
16. Radiology devices

Article 3 Medical devices are classified into the following classes according to their risk level:

1. Class I: Low risk
2. Class II: Medium risk
3. Class III: High risk

Article 4 Product items of the medical device classification are specified in the Annex.

In addition to rules stated in the Annex, medical devices whose function, intended use, or working principle are special may have their classification determined according to the following rules:

1. If two or more categories, classes, or product items are applicable to the same medical device, the highest class of risk level is assigned.
2. The accessory to a medical device, intended specifically by the manufacturer for use with a particular medical device, is classified the same as the particular medical device, unless otherwise specified in the Annex.
3. The classification of a combined product, which contains two or more medical devices packaged together while having two or more categories, classes, or product items applicable, is assigned the highest class of risk level among these devices.
4. A medical device containing medicine while having the primary mode of action of a medical device is determined to be a Class III medical device, unless otherwise specified in the Annex.

Article 5 Medical device firms or the public may make an inquiry to the central competent authority regarding classification of medical devices or other relevant matters.

Inquirers of the preceding paragraph shall fill out an inquiry form, provide the following related documents and information, and pay the required fees for submission to the central competent authority:

1. Instructions for use of the manufacturer: including operating instructions, function, and working principle. If they are not in the traditional Chinese or English version, a translation copy in traditional Chinese or English shall be provided separately.
2. Other reference information: Reference information from the United States of America, European Union, or other countries on the classification of the inquired product. If such reference information is not available, it is not required to be provided.

In addition to the above documents and information, when necessary, the central competent authority may request the inquirer to provide other relevant documents and information.

Article 6 If the function, intended use, or working principle of the medical device does not meet identification criteria of the product items listed in the Annex, its classification shall be determined to be a Class III medical device. However, if a similar product has received license or been listed domestically, its classification shall be determined according to the risk level of the similar product, or if a classification inquiry has been made to the central competent authority in accordance with the provisions of the preceding paragraph, it shall be determined according to the risk level as responded by the central competent authority.

Article 7 These Regulations shall enter into force from the effective date of this Act.

Annex

Classification Number	Classification Name	Class	Identification
A.0001	Phencyclidine test system	2	Phencyclidine test system is a device to measure the concentration of Phencyclidine (an anesthetic agent) or Phencyclidine analog in blood, urine, or/and stomach contents. This device is to monitor the concentration of Phencyclidine or Phencyclidine analog in diseases treatment or diagnosis.
A.0002	Clinical Chemistry Electrolyte System	1	Clinical chemistry electrolyte system is intended to perform a specific function in an assay that is used for the qualitative and/or quantitative determination of electrolytes and other ions in a clinical specimen.
A.1020	Acid phosphatase (total or prostatic) test system	2	An acid phosphatase (total or prostatic) test system is a device intended to measure the activity of the acid phosphatase enzyme in plasma and serum.
A.1025	Adrenocorticotropic hormone (ACTH) test system	2	An adrenocorticotropic hormone (ACTH) test system is a device intended to measure adrenocorticotropic hormone in plasma and serum. ACTH measurements are used in the differential diagnosis and treatment of certain disorders of the adrenal glands such as Cushing's syndrome, adrenocortical insufficiency, and the ectopic ACTH syndrome.
A.1030	Alanine amino transferase (ALT/SGPT) test system	1	An alanine amino transferase (ALT/SGPT) test system is a device intended to measure the activity of the enzyme alanine amino transferase (ALT) (also known as a serum glutamic pyruvic transaminase or SGPT) in serum and plasma. Alanine amino transferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases.
A.1035	Albumin test system	2	An albumin test system is a device intended to measure the albumin concentration in serum and plasma. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.
A.1040	Aldolase test system	1	An aldolase test system is a device intended to measure the activity of the enzyme aldolase in serum or plasma. Aldolase measurements are used in the diagnosis and treatment of the early stages of acute hepatitis and for certain muscle diseases such as progressive Duchenne-type muscular dystrophy.
A.1045	Aldosterone test system	2	An aldosterone test system is a device intended to measure the hormone aldosterone in serum and urine. Aldosterone measurements are used in the diagnosis and treatment of primary aldosteronism (a disorder caused by the excessive secretion of aldosterone by the adrenal gland), hypertension caused by primary aldosteronism, selective hypoaldosteronism, edematous states, and other conditions of electrolyte imbalance.
A.1050	Alkaline phosphatase or isoenzymes test system	2	An alkaline phosphatase or isoenzymes test system is a device intended to measure alkaline phosphatase or its isoenzymes (a group of enzymes with similar biological activity) in serum or plasma. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

A.1055	Newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry.	2	A newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry is a device that consists of stable isotope internal standards, control materials, extraction solutions, flow solvents, instrumentation, software packages, and other reagents and materials. The device is intended for the measurement and evaluation of amino acids, free carnitine, and acylcarnitine concentrations from newborn whole blood filter paper samples. The quantitative analysis of amino acids, free carnitine, and acylcarnitines and their relationship with each other provides analyte concentration profiles that may aid in screening newborns for one or more inborn errors of amino acid, free carnitine, and acyl-carnitine metabolism.
A.1060	Delta-aminolevulinic acid test system	1	Adelta -aminolevulinic acid test system is a device intended to measure the level ofdelta -aminolevulinic acid (a precursor of porphyrin) in urine.Delta -aminolevulinic acid measurements are used in the diagnosis and treatment of lead poisoning and certain porphyrias (diseases affecting the liver, gastrointestinal, and nervous systems that are accompanied by increased urinary excretion of various heme compounds includingdelta -aminolevulinic acid).
A.1065	Ammonia test system	1	An ammonia test system is a device intended to measure ammonia levels in blood, serum, and plasma, Ammonia measurements are used in the diagnosis and treatment of severe liver disorders, such as cirrhosis, hepatitis, and Reye's syndrome.
A.1070	Amylase test system	2	An amylase test system is a device intended to measure the activity of the enzyme amylase in serum and urine. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).
A.1075	Androstenedione test system	1	An androstenedione test system is a device intended to measure androstenedione (a substance secreted by the testes, ovary, and adrenal glands) in serum. Adrostenedione measurements are used in the diagnosis and treatment of females with excessive levels of androgen (male sex hormone) production.
A.1080	Androsterone test system	1	An androsterone test system is a device intended to measure the hormone adrosterone in serum, plasma, and urine. Androsterone measurements are used in the diagnosis and treatment of gonadal and adrenal diseases.
A.1085	Angiotensin I and renin test system	2	An angiotensin I and renin test system is a device intended to measure the level of angiotensin I generated by renin in plasma. Angiotensin I measurements are used in the diagnosis and treatment of certain types of hypertension.
A.1090	Angiotensin converting enzyme (A.C.E) test system	2	An angiotensin converting enzyme (A.C.E.) test system is a device intended to measure the activity of angiotensin converting enzyme in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of diseases such as sarcoidosis, a disease characterized by the formation of nodules in the lungs, bones, and skin, and Gaucher's disease, a hereditary disorder affecting the spleen.
A.1095	Ascorbic acid test system	1	An ascorbic acid test system is a device intended to measure the level of ascorbic acid (vitamin C) in plasma, serum, and urine. Ascorbic acid measurements are used in the diagnosis and treatment of ascorbic acid dietary deficiencies.

A.1100	Asparate amino transferase (AST/SGOT) test system	2	An aspartate amino transferase (AST/SGOT) test system is a device intended to measure the activity of the enzyme aspartate amino transferase (AST) (also known as a serum glutamic oxaloacetic transferase or SGOT) in serum and plasma. Aspartate amino transferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.
A.1110	Bilirubin (total or direct) test system	2	A bilirubin (total or direct) test system is a device intended to measure the levels of bilirubin (total or direct) in plasma or serum. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal distruction of red blood cells, if used in the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.
A.1113	Bilirubin (total and unbound) in the neonate test system	1	A bilirubin (total and unbound) in the neonate test system is a device intended to measure the levels of bilirubin (total and unbound) in the blood (serum) of newborn infants to aid in indicating the risk of bilirubin encephalopathy (kernicterus).
A.1115	Urinary bilirubin and its conjugates (nonquantitative) test system	1	A urinary bilirubin and its conjugates (nonquantitative) test system is a device intended to measure the levels of bilirubin conjugates in urine. Measurements of urinary bilirubin and its conjugates (nonquantitative) are used in the diagnosis and treatment of certain liver diseases.
A.1117	B-type natriuretic peptide test system	2	The B-type natriuretic peptide (BNP) test system is an in vitro diagnostic device intended to measure BNP in whole blood and plasma. Measurements of BNP are used as an aid in the diagnosis of patients with congestive heart failure.
A.1118	Biotinidase test system	2	The biotinidase test system is an in vitro diagnostic device intended to measure the activity of the enzyme biotinidase in blood. Measurements of biotinidase are used in the treatment and diagnosis of biotinidase deficiency, an inborn error of metabolism in infants, characterized by the inability to utilize dietary protein bound vitamin or to recycle endogenous biotin. The deficiency may result in irreversible neurological impairment.
A.1120	Blood gases (PCO2,PO2) and blood pH test system	2	A blood gases (PCO2, PO2) and blood pH test system is a device intended to measure certain gases in blood, serum, plasma or pH of blood, serum, and plasma. Measurements of blood gases (PCO2, PO2) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.
A.1130	Blood volume test system	1	A blood volume test system is a device intended to measure the circulating blood volume. Blood volume measurements are used in the diagnosis and treatment of shock, hemorrhage, and polycythemia vera (a disease characterized by an absolute increase in erythrocyte mass and total blood volume).
A.1135	C-peptides of proinsulin test system	1	A C-peptides of proinsulin test system is a device intended to measure C-peptides of proinsulin levels in serum, plasma, and urine. Measurements of C-peptides of proinsulin are used in the diagnosis and treatment of patients with abnormal insulin secretion, including diabetes mellitus.

A.1140	Calcitonin test system	2	A calcitonin test system is a device intended to measure the thyroid hormone calcitonin (thyrocalcitonin) levels in plasma and serum. Calcitonin measurements are used in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism (excessive activity of the parathyroid gland).
A.1145	Calcium test system	2	A calcium test system is a device intended to measure the total calcium level in serum. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).
A.1150	Calibrator	2	A calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.
A.1155	Human chorionic gonadotropin (HCG) test system	2,3	(a)Human chorionic gonadotropin (HCG) test system intended for the early detection of pregnancy --(1)Identification: A human chorionic gonadotropin (HCG) test system is a device intended for the early detection of pregnancy is intended to measure HCG, a placental hormone, in plasma or urine. (2)Classification: Class 2. (b)Human chorionic gonadotropin (HCG) test system intended for any uses other than early detection of pregnancy --(1)Identification: A human chorionic goadotropin (HCG) test system is a device intended for any uses other than early detection of pregnancy (such as an aid in the diagnosis, prognosis, and management of treatment of persons with certain tumors or carcinomas) is intended to measure HCG, a placental hormone, in plasma or urine. (2)Classification:Class 3.
A.1160	Bicarbonate/carbon dioxide test system	2	A bicarbonate/carbon dioxide test system is a device intended to measure bicarbonate/carbon dioxide in plasma, serum, and whole blood. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.
A.1163	Cardiac allograft gene expression profiling test system	2	A cardiac allograft gene expression profiling test system is a device that measures the ribonucleic acid (RNA) expression level of multiple genes and combines this information to yield a signature (pattern, classifier, index, score) to aid in the identification of a low probability of acute cellular rejection (ACR) in heart transplant recipients with stable allograft function.
A.1165	Catecholamines (total) teset system	1	A catecholamines (total) test system is a device intended to determine whether a group of similar compounds (epinephrine, norepinephrine, and dopamine) are present in urine and plasma. Catecholamine determinations are used in the diagnosis and treatment of adrenal medulla and hypertensive disorders, and for catecholamine-secreting tumors (pheochromo-cytoma, neuroblastoma, ganglioneuroma, and retinoblastoma).
A.1170	Chloride test system	2	A chloride test system is a device intended to measure the level of chloride in plasma, serum, sweat, and urine. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

A.1175	Cholesterol (total) test system	1	A cholesterol (total) test system is a device intended to measure cholesterol in plasma and serum. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
A.1177	Cholylglycine test system	2	A cholylglycine test system is a device intended to measure the bile acid cholylglycine in serum. Measurements obtained by this device are used in the diagnosis and treatment of liver disorders, such as cirrhosis or obstructive liver disease.
A.1180	Chymotrypsin test system	1	A chymotrypsin test system is a device intended to measure the activity of the enzyme chymotrypsin in blood and other body fluids and in feces. Chymotrypsin measurements are used in the diagnosis and treatment of pancreatic exocrine insufficiency.
A.1185	Compound S (11-deoxycortisol) test system	1	A compound S (11-dioxycortisol) test system is a device intended to measure the level of compound S (11-dioxycortisol) in plasma. Compound S is a steroid intermediate in the biosynthesis of the adrenal hormone cortisol. Measurements of compound S are used in the diagnosis and treatment of certain adrenal and pituitary gland disorders resulting in clinical symptoms of masculinization and hypertension.
A.1187	Conjugated sulfolithocholic acid (SLCG) test system	2	A conjugated sulfolithocholic acid (SLCG) test system is a device intended to measure the bile acid SLCG in serum. Measurements obtained by this device are used in the diagnosis and treatment of liver disorders, such as cirrhosis or obstructive liver disease.
A.1190	Copper test system	1	A copper test system is a device intended to measure copper levels in plasma, serum, and urine. Measurements of copper are used in the diagnosis and treatment of anemia, infections, inflammations, and Wilson's disease (a hereditary disease primarily of the liver and nervous system). Test results are also used in monitoring patients with Hodgkin's disease (a disease primarily of the lymph system).
A.1195	Corticoids test system	1	A corticoids test system is a device intended to measure the levels of corticoids (hormones of the adrenal cortex) in serum and p lasma. Measurements of corticoids are used in the diagnosis and treatment of disorders of the cortex of the adrenal glands, especially those associated with hypertension and electrolyte disturbances.
A.1200	Corticosterone test system	1	A corticosterone test system is a device intended to measure corticosterone (a steroid secreted by the adrenal gland) levels in plasma. Measurements of corticosterone are used in the diagnosis and treatment of adrenal disorders such as adrenal cortex disorders and blocks in cortisol synthesis.
A.1205	Cortisol (hydrocortisone and hydroxycorticosterone) test system	2	A cortisol (hydrocortisone and hydroxycorticosterone) test system is a device intended to measure the cortisol hormones secreted by the adrenal gland in plasma and urine. Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.

A.1210	Creatine test system	1	A creatine test system is a device intended to measure creatine (a substance synthesized in the liver and pancreas and found in biological fluids) in plasma, serum, and urine. Measurements of creatine are used in the diagnosis and treatment of muscle diseases and endocrine disorders including hyperthyroidism.
A.1215	Creatine phosphokinase/ creatine kinase or isoenzymes test system	2	A creatine phosphokinase/creatine kinase or isoenzymes test system is a device intended to measure the activity of the enzyme creatine phosphokinase or its isoenzymes (a group of enzymes with similar biological activity) in plasma and serum. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.
A.1220	Acute Kidney Injury Test System	2	An acute kidney injury test system is a device that is intended to measure one or more analytes in human samples as an aid in the assessment of a patient's risk for developing acute kidney injury. Test results are intended to be used in conjunction with other clinical and diagnostic findings, consistent with professional standards of practice, including confirmation by alternative methods.
A.1225	Creatinine test system	2	A creatinine test system is a device intended to measure creatinine levels in plasma and urine. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.
A.1230	Cyclic AMP test system	2	A cyclic AMP test system is a device intended to measure the level of adenosine 3', 5'-monophosphate (cyclic AMP) in plasma, urine, and other body fluids. Cyclic AMP measurements are used in the diagnosis and treatment of endocrine disorders, including hyperparathyroidism (overactivity of the parathyroid gland). Cyclic AMP measurements may also be used in the diagnosis and treatment of Graves' disease (a disorder of the thyroid) and in the differentiation of causes of hypercalcemia (elevated levels of serum calcium.)
A.1235	Cyclosporine test system	2	A cyclosporine test system is a device intended to quantitatively determine cyclosporine concentrations as an aid in the management of transplant patients receiving therapy with this drug. This generic type of device includes immunoassays and chromatographic assays for cyclosporine.
A.1240	Cystine test system	1	A cystine test system is a device intended to measure the amino acid cystine in urine. Cystine measurements are used in the diagnosis of cystinuria (occurrence of cystine in urine). Patients with cystinuria frequently develop kidney calculi (stones).
A.1245	Dehydroepiandrosterone (free and sulfate) test system	1	A dehydroepiandrosterone (free and sulfate) test system is a device intended to measure dehydroepiandrosterone (DHEA) and its sulfate in urine, serum, plasma, and amniotic fluid. Dehydroepiandrosterone measurements are used in the diagnosis and treatment of DHEA-secreting adrenal carcinomas.
A.1250	Deoxycorticosterone test system	1	A desoxycorticosterone test system is a device intended to measure desoxycorticosterone (DOC) in plasma and urine. DOC measurements are used in the diagnosis and treatment of patients with hypermineralocorticoidism (excess retention of sodium and loss of potassium) and other disorders of the adrenal gland.

A.1255	2,3-Diphosphoglyceric acid test system	1	A 2,3-diphosphoglyceric acid test system is a device intended to measure 2,3-diphosphoglyceric acid (2,3-DPG) in erythrocytes (red blood cells). Measurements of 2,3-diphosphoglyceric acid are used in the diagnosis and treatment of blood disorders that affect the delivery of oxygen by erythrocytes to tissues and in monitoring the quality of stored blood.
A.1260	Estradiol test system	1	An estradiol test system is a device intended to measure estradiol, an estrogenic steroid, in plasma. Estradiol measurements are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.
A.1265	Estriol test system	1	An estriol test system is a device intended to measure estriol, an estrogenic steroid, in plasma, serum, and urine of pregnant females. Estriol measurements are used in the diagnosis and treatment of fetoplacental distress in certain cases of high-risk pregnancy.
A.1270	Estrogens (total, in pregnancy) test system	1	As estrogens (total, in pregnancy) test system is a device intended to measure total estrogens in plasma, serum, and urine during pregnancy. The device primarily measures estrone plus estradiol. Measurements of total estrogens are used to aid in the diagnosis and treatment of fetoplacental distress in certain cases of high-risk pregnancy.
A.1275	Estrogens (total, nonpregnancy) test system	1	As estrogens (total, nonpregnancy) test system is a device intended to measure the level of estrogens (total estrone, estradiol, and estriol) in plasma, serum, and urine of males and nonpregnant females. Measurement of estrogens (total, nonpregnancy) is used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea (absence of menses) differentiation of primary and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors, and precocious puberty in females.
A.1280	Estrone test system	1	An estrone test system is a device intended to measure estrone, an estrogenic steroid, in plasma. Estrone measurements are used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea, differentiation of primary and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors, and precocious puberty in females.
A.1285	Etiocholanolone test system	1	An etiocholanolone test system is a device intended to measure etiocholanolone in serum and urine. Etiocholanolone is a metabolic product of the hormone testosterone and is excreted in the urine. Etiocholanolone measurements are used in the diagnosis and treatment of disorders of the testes and ovaries.
A.1290	Fatty acids test system	1	A fatty acids test system is a device intended to measure fatty acids in plasma and serum. Measurements of fatty acids are used in the diagnosis and treatment of various disorders of lipid metabolism.
A.1295	Folic acid test system	2	A folic acid test system is a device intended to measure the vitamin folic acid in plasma and serum. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia, which is characterized by the presence of megaloblasts (an abnormal red blood cell series) in the bone marrow.

A.1300	Follicle-stimulating hormone test system	1	A follicle-stimulating hormone test system is a device intended to measure follicle-stimulating hormone (FSH) in plasma, serum, and urine. FSH measurements are used in the diagnosis and treatment of pituitary gland and gonadal disorders.
A.1305	Formiminoglutamic acid (FIGLU) test system	1	A formiminoglutamic acid (FIGLU) test system is a device intended to measure formiminolutamic acid in urine. FIGLU measurements obtained by this device are used in the diagnosis of anemias, such as pernicious anemia and congenital hemolytic anemia.
A.1310	Galactose test system	1	A galactose test system is a device intended to measure galactose in blood and urine. Galactose measurements are used in the diagnosis and treatment of the hereditary disease galactosemia (a disorder of galactose metabolism) in infants.
A.1315	Galactose-1-phosphate uridyl transferase test system	2	A galactose-1-phosphate uridyl transferase test system is a device intended to measure the activity of the enzyme galactose-1-phosphate uridyl transferase in erythrocytes (red blood cells). Measurements of galactose-1-phosphate uridyl transferase are used in the diagnosis and treatment of the hereditary disease galactosemia (disorder of galactose metabolism) in infants.
A.1320	Gastric acidity test system	1	A gastric acidity test system is a device intended to measure the acidity of gastric fluid. Measurements of gastric acidity are used in the diagnosis and treatment of patients with peptic ulcer, Zollinger-Ellison syndrome (peptic ulcer due to gastrin-secreting tumor of the pancreas), and related gastric disorders.
A.1325	Gastrin test system	1	A gastrin test system is a device intended to measure the hormone gastrin in plasma and serum. Measurements of gastrin are used in the diagnosis and treatment of patients with ulcers, pernicious anemia, and the Zollinger-Ellison syndrome (peptic ulcer due to a gastrin-secreting tumor of the pancreas).
A.1330	Globulin test system	1	A globulin test system is a device intended to measure globulins (proteins) in plasma and serum. Measurements of globulin are used in the diagnosis and treatment of patients with numerous illnesses including severe liver and renal disease, multiple myeloma, and other disorders of blood globulins.
A.1335	Glucagon test system	1	A glucagon test system is a device intended to measure the pancreatic hormone glucagon in plasma and serum. Glucagon measurements are used in the diagnosis and treatment of patients with various disorders of carbohydrate metabolism, including diabetes mellitus, hypoglycemia, and hyperglycemia.
A.1340	Urinary glucose (nonquantitative) test system	2	A urinary glucose (nonquantitative) test system is a device intended to measure glucosuria (glucose in urine). Urinary glucose (nonquantitative) measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia.
A.1345	Glucose test system	2	A glucose test system is a device intended to measure glucose quantitatively in blood and other body fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

A.1350	Continuous Glucose Monitor Secondary Display	2	A continuous glucose monitor secondary display is identified as a device intended to be used for passive real-time monitoring of continuous glucose monitoring data. It must not be capable of serving as a stand-alone primary display device. The primary display device, which is not a part of the continuous glucose monitor secondary display, directly receives the glucose data (for example, it communicates directly with transmitter) from the continuous glucose meter, which is not a part of the continuous glucose monitor secondary display, and is the primary means of viewing the continuous glucose monitor data and alerting the patient to a low or high glucose value. A continuous glucose monitor secondary display can be used by caregivers of people with diabetes to monitor a person's continuous glucose monitoring data. A device is not a continuous glucose monitor secondary display if the data from the primary display device is modified (for example, predicting future glucose values) or the patient can use the secondary display in lieu of a primary display device (for example, the primary display device is blinded or the primary display does not have to be near the person wearing the sensor and transmitter).
A.1358	Insulin therapy adjustment device	2	An insulin therapy adjustment device is a device intended to incorporate biological inputs, including glucose measurement data from a continuous glucose monitor, to recommend insulin therapy adjustments as an aid in optimizing insulin therapy regimens for patients with diabetes mellitus.
A.1360	Gamma-glutamyl transpeptidase and isoenzymes test system	1	A gamma-glutamyl transpeptidase and isoenzymes test system is a device intended to measure the activity of the enzyme gamma-glutamyl transpeptidase (GGTP) in plasma and serum. Gamma-glutamyl transpeptidase and isoenzymes measurements are used in the diagnosis and treatment of liver diseases such as alcoholic cirrhosis and primary and secondary liver tumors.
A.1365	Glutathione test system	1	A glutathione test system is a device intended to measure glutathione (the tripeptide of glycine, cysteine, and glutamic acid) in erythrocytes (red blood cells). Glutathione measurements are used in the diagnosis and treatment of certain drug-induced hemolytic (erythrocyte destroying) anemias due to an inherited enzyme deficiency.
A.1370	Human growth hormone test system	1	A human growth hormone test system is a device intended to measure the levels of human growth hormone in plasma. Human growth hormone measurements are used in the diagnosis and treatment of disorders involving the anterior lobe of the pituitary gland.
A.1373	Hemoglobin A1c test system	2	A hemoglobin A1c test system is a device used to measure the percentage concentration of hemoglobin A1c in blood. Measurement of hemoglobin A1c is used as an aid in the diagnosis of diabetes mellitus and as an aid in the identification of patients at risk for developing diabetes mellitus.
A.1375	Histidine test system	1	A histidine test system is a device intended to measure free histidine (an amino acid) in plasma and urine. Histidine measurements are used in the diagnosis and treatment of hereditary histidinemia characterized by excess histidine in the blood and urine often resulting in mental retardation and disordered speech development.

A.1377	Urinary homocystine (nonquantitative) test system	2	A urinary homocystine (nonquantitative) test system is a device intended to identify homocystine (an analogue of the amino acid cystine) in urine. The identification of urinary homocystine is used in the diagnosis and treatment of homocystinuria (homosystine in urine), a heritable metabolic disorder which may cause mental retardation.
A.1380	Hydroxybutyric dehydrogenase test system	1	A hydroxybutyric dehydrogenase test system is a device intended to measure the activity of the enzyme alpha-hydroxybutric dehydrogenase (HBD) in plasma or serum. HBD measurements are used in the diagnosis and treatment of myocardial infarction, renal damage (such as rejection of transplants), certain hematological diseases (such as acute leukemias and megaloblastic anemias) and, to a lesser degree, liver disease.
A.1385	17-Hydroxycorticosteroids (17-ketogenic steroids) test system	1	A 17-hydroxycorticosteroids (17-ketogenic steroids) test system is a device intended to measure corticosteroids that possess a dihydroxyacetone moiety on the steroid nucleus in urine. Corticosteroids with this chemical configuration include cortisol, cortisone 11-desoxycortisol, desoxycorticosterone, and their tetrahydroderivatives. This group of hormones is synthesized by the adrenal gland. Measurements of 17-hydroxycorticosteroids (17-ketogenic steroids) are used in the diagnosis and treatment of various diseases of the adrenal or pituitary glands and gonadal disorders.
A.1390	5-Hydroxyindole acetic acid/serotonin test system	1	A 5-hydroxyindole acetic acid/serotonin test system is a device intended to measure 5-hydroxyindole acetic acid/serotonin in urine. Measurements of 5-hydroxyindole acetic acid/serotonin are used in the diagnosis and treatment of carcinoid tumors of endocrine tissue.
A.1395	17-Hydroxyprogesterone test system	1	A 17-hydroxyprogesterone test system is a device intended to measure 17-hydroxyprogesterone (a steroid) in plasma and serum. Measurements of 17-hydroxyprogesterone are used in the diagnosis and treatment of various disorders of the adrenal glands or the ovaries.
A.1400	Hydroxyproline test system	1	A hydroxyproline test system is a device intended to measure the amino acid hydroxyproline in urine. Hydroxyproline measurements are used in the diagnosis and treatment of various collagen (connective tissue) diseases, bone disease such as Paget's disease, and endocrine disorders such as hyperparathyroidism and hyperthyroidism.
A.1405	Immunoreactive insulin test system	1	An immunoreactive insulin test system is a device intended to measure immunoreactive insulin in serum and plasma. Immunoreactive insulin measurements are used in the diagnosis and treatment of various carbohydrate metabolism disorders, including diabetes mellitus, and hypoglycemia.
A.1410	Iron (non-heme) test system	1	An iron (non-heme) test system is a device intended to measure iron (non-heme) in serum and plasma. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease.

A.1415	Iron-binding capacity test system	1	An iron-binding capacity test system is a device intended to measure iron-binding capacity in serum. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia.
A.1420	Isocitric dehydrogenase test system	1	An isocitric dehydrogenase test system is a device intended to measure the activity of the enzyme isocitric dehydrogenase in serum and plasma. Isocitric dehydrogenase measurements are used in the diagnosis and treatment of liver disease such as viral hepatitis, cirrhosis, or acute inflammation of the biliary tract; pulmonary disease such as pulmonary infarction (local arrest or sudden insufficiency of the blood supply to the lungs), and diseases associated with pregnancy.
A.1430	17-Ketosteroids test system	1	A 17-ketosteroids test system is a device intended to measure 17-ketosteroids in urine. Measurements of 17-ketosteroids are used in the diagnosis and treatment of disorders of the adrenal cortex and gonads and of other endocrine disorders, including hypertension, diabetes, and hypothyroidism.
A.1435	Ketones (nonquantitative) test system	1	A ketones (nonquantitative) test system is a device intended to identify ketones in urine and other body fluids. Identification of ketones is used in the diagnosis and treatment of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by increased production of ketone bodies such as acetone) and for monitoring patients on ketogenic diets and patients with diabetes.
A.1440	Lactate dehydrogenase test system	1	A lactate dehydrogenase test system is a device intended to measure the activity of the enzyme lactate dehydrogenase in serum. Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction, and tumors of the lung or kidneys.
A.1445	Lactate dehydrogenase isoenzymes test system	2	A lactate dehydrogenase isoenzymes test system is a device intended to measure the activity of lactate dehydrogenase isoenzymes (a group of enzymes with similar biological activity) in serum. Measurements of lactate dehydrogenase isoenzymes are used in the diagnosis and treatment of liver diseases, such as viral hepatitis, and myocardial infarction.
A.1450	Lactic acid test system	1	A lactic acid test system is a device intended to measure lactic acid in whole blood and plasma. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).
A.1455	Lecithin/sphingomyelin ratio in amniotic fluid test system	2	A lecithin/sphingomyelin ratio in amniotic fluid test system is a device intended to measure the lecithin/sphingomyelin ratio in amniotic fluid. Lecithin and sphingomyelin are phospholipids (fats or fat-like substances containing phosphorus). Measurements of the lecithin/sphingomyelin ratio in amniotic fluid are used in evaluating fetal maturity.

A.1460	Leucine aminopeptidase test system	1	A leucine aminopeptidase test system is a device intended to measure the activity of the enzyme leucine amino-peptidase in serum, plasma, and urine. Leucine aminopeptidase measurements are used in the diagnosis and treatment of liver diseases such as viral hepatitis and obstructive jaundice.
A.1465	Lipase test system	1	A lipase test system is a device intended to measure the activity of the enzymes lipase in serum. Lipase measurements are used in diagnosis and treatment of diseases of the pancreas such as acute pancreatitis and obstruction of the pancreatic duct.
A.1470	Lipid (total) test system	1	A lipid (total) test system is a device intended to measure total lipids (fats or fat-like substances) in serum and plasma. Lipid (total) measurements are used in the diagnosis and treatment of various diseases involving lipid metabolism and atherosclerosis.
A.1475	Lipoprotein test system	1	A lipoprotein test system is a chemical analysis device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
A.1485	Luteinizing hormone test system	1	A luteinizing hormone test system is a device intended to measure luteinizing hormone in serum and urine. Luteinizing hormone measurements are used in the diagnosis and treatment of gonadal dysfunction.
A.1490	Lysozyme (muramidase) test system	1	A lysozyme (muramidase) test system is a device intended to measure the activity of the bacteriolytic enzyme lysozyme (muramidase) in serum, plasma, leukocytes, and urine. Lysozyme measurements are used in the diagnosis and treatment of monocytic leukemia and kidney disease.
A.1495	Magnesium test system	1	A magnesium test system is a device intended to measure magnesium levels in serum and plasma. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).
A.1500	Malic dehydrogenase test system	1	A malic dehydrogenase test system is a device that is intended to measure the activity of the enzyme malic dehydrogenase in serum and plasma. Malic dehydrogenase measurements are used in the diagnosis and treatment of muscle and liver diseases, myocardial infarctions, cancer, and blood disorders such as myelogenous (produced in the bone marrow) leukemia.
A.1505	Mucopolysaccharides (nonquantitative) test system	1	A mucopolysaccharides (nonquantitative) test system is a device intended to measure the levels of mucopolysaccharides in urine. Mucopolysaccharide measurements in urine are used in the diagnosis and treatment of various inheritable disorders that affect bone and connective tissues, such as Hurler's, Hunter's, Sanfilippo's, Scheie's Morquio's and Maroteaux-Lamy syndromes.
A.1509	Methylmalonic acid (nonquantitative) test system	2	A methylmalonic acid (nonquantitative) test system is a device intended to identify methylmalonic acid in urine. The identification of methylmalonic acid in urine is used in the diagnosis and treatment of methylmalonic aciduria, a heritable metabolic disorder which, if untreated, may cause mental retardation.

A.1510	Nitrite (nonquantitative) test system	1	A nitrite (nonquantitative) test system is a device intended to identify nitrite in urine. Nitrite identification is used in the diagnosis and treatment of uninary tract infection of bacterial origin.
A.1515	Nitrogen (amino-nitrogen) test system	1	A nitrogen (amino-nitrogen) test system is a device intended to measure amino acid nitrogen levels in serum, plasma, and urine. Nitrogen (amino-nitrogen) measurements are used in the diagnosis and treatment of certain forms of severe liver disease and renal disorders.
A.1520	5'-Nucleotidase test system	1	A 5'-nucleotidase test system is a device intended to measure the activity of the enzyme 5'-nucleotidase in serum and plasma. Measurements of 5'-nucleotidase are used in the diagnosis and treatment of liver diseases and in the differentiations between liver and bone diseases in the presence of elevated serum alkaline phosphatase activity.
A.1530	Plasma oncometry test system	1	A plasma oncometry test system is a device intended to measure plasma oncotic pressure. Plasma oncotic pressure is that portion of the total fluid pressure contributed by proteins and other molecules too large to pass through a specified membrane. Measurements of plasma oncotic pressure are used in the diagnosis and treatment of dehydration and circulatory disorders related to low serum protein levels and increased capillary permeability, such as edema and shock.
A.1535	Ornithine carbamyl transferase test system	1	An ornithine carbamyl transferase test system is a device intended to measure the activity of the enzyme ornithine carbamyl transferase (OCT) in serum. Ornithine carbamyl transferase measurements are used in the diagnosis and treatment of liver diseases, such as infectious hepatitis, acute cholecystitis (inflammation of the gall bladder), cirrhosis, and liver metastases.
A.1540	Osmolality test system	1	An osmolality test system is a device intended to measure ionic and nonionic solute concentration in body fluids, such as serum and urine. Osmolality measurement is used as an adjunct to other tests in the evaluation of a variety of diseases, including kidney diseases (e.g., chronic progressive renal failure), diabetes insipidus, other endocrine and metabolic disorders, and fluid imbalances.
A.1542	Oxalate test system	1	An oxalate test system is a device intended to measure the concentration of oxalate in urine. Measurements of oxalate are used to aid in the diagnosis or treatment of urinary stones or certain other metabolic disorders.
A.1545	Parathyroid hormone test system	2	A parathyroid hormone test system is a device intended to measure the levels of parathyroid hormone in serum and plasma. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism.
A.1550	Urinary pH (nonquantitative) test system	1	A urinary pH (nonquantitative) test system is a device intended to estimate the pH of urine. Estimations of pH are used to evaluate the acidity or alkalinity of urine as it relates to numerous renal and metabolic disorders and in the monitoring of patients with certain diets.

A.1555	Phenylalanine test system	2	A phenylalanine test system is a device intended to measure free phenylalanine (an amino acid) in serum, plasma, and urine. Measurements of phenylalanine are used in the diagnosis and treatment of congenital phenylketonuria which, if untreated, may cause mental retardation.
A.1560	Urinary phenylketones (nonquantitative) test system	1	A urinary phenylketones (nonquantitative) test system is a device intended to identify phenylketones (such as phenylpyruvic acid) in urine. The identification of urinary phenylketones is used in the diagnosis and treatment of congenital phenylketonuria which, if untreated, may cause mental retardation.
A.1565	6-Phosphogluconate dehydrogenase test system	1	A 6-phosphogluconate dehydrogenase test system is a device intended to measure the activity of the enzyme 6-phosphogluconate dehydrogenase (6 PGD) in serum and erythrocytes. Measurements of 6-phosphogluconate dehydrogenase are used in the diagnosis and treatment of certain liver diseases (such as hepatitis) and anemias.
A.1570	Phosphohexose isomerase test system	1	A phosphohexose isomerase test system is a device intended to measure the activity of the enzyme phosphohexose isomerase in serum. Measurements of phosphohexose isomerase are used in the diagnosis and treatment of muscle diseases such as muscular dystrophy, liver diseases such as hepatitis or cirrhosis, and metastatic carcinoma.
A.1575	Phospholipid test system	1	A phospholipid test system is a device intended to measure phospholipids in serum and plasma. Measurements of phospholipids are used in the diagnosis and treatment of disorders involving lipid (fat) metabolism.
A.1580	Phosphorus (inorganic) test system	1	A phosphorus (inorganic) test system is a device intended to measure inorganic phosphorus in serum, plasma, and urine. Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.
A.1585	Human placental lactogen test system	2	A human placental lactogen test system is a device intended to measure the hormone human placental lactogen (HPL), (also known as human chorionic somatomammotrophin (HCS)), in maternal serum and maternal plasma. Measurements of human placental lactogen are used in the diagnosis and clinical management of high-risk pregnancies involving fetal distress associated with placental insufficiency. Measurements of HPL are also used in pregnancies complicated by hypertension, proteinuria, edema, post-maturity, placental insufficiency, or possible miscarriage.
A.1590	Porphobilinogen test system	1	A porphobilinogen test system is a device intended to measure porphobilinogen (one of the derivatives of hemoglobin which can make the urine a red color) in urine. Measurements obtained by this device are used in the diagnosis and treatment of porphyrias (primarily inherited diseases associated with disturbed porphyrine metabolism), lead poisoning, and other diseases characterized by alterations in the heme pathway.

A.1595	Porphyrins test system	1	A porphyrins test system is a device intended to measure porphyrins (compounds formed during the biosynthesis of heme, a constituent of hemoglobin, and related compounds) in urine and feces. Measurements obtained by this device are used in the diagnosis and treatment of lead poisoning, porphyrias (primarily inherited diseases associated with disturbed porphyrin metabolism), and other diseases characterized by alterations in the heme pathway.
A.1600	Potassium test system	2	A potassium test system is a device intended to measure potassium in serum, plasma, and urine. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.
A.1605	Pregnanediol test system	1	A pregnanediol test system is a device intended to measure pregnanediol (a major urinary metabolic product of progesterone) in urine. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the ovaries or placenta.
A.1610	Pregnanetriol test system	1	A pregnanetriol test system is a device intended to measure pregnanetriol (a precursor in the biosynthesis of the adrenal hormone cortisol) in urine. Measurements obtained by this device are used in the diagnosis and treatment of congenital adrenal hyperplasia (congenital enlargement of the adrenal gland).
A.1615	Pregnenolone test system	1	A pregnenolone test system is a device intended to measure pregnenolone (a precursor in the biosynthesis of the adrenal hormone cortisol and adrenal androgen) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of diseases of the adrenal cortex or the gonads.
A.1620	Progesterone test system	1	A progesterone test system is a device intended to measure progesterone (a female hormone) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the ovaries or placenta.
A.1625	Prolactin (lactogen) test system	1	A prolactin (lactogen) test system is a device intended to measure the anterior pituitary polypeptide hormone prolactin in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the anterior pituitary gland or of the hypothalamus portion of the brain.
A.1630	Protein (fractionation) test system	1	A protein (fractionation) test system is a device intended to measure protein fractions in blood, urine, cerebrospinal fluid, and other body fluids. Protein fractionations are used as an aid in recognizing abnormal proteins in body fluids and genetic variants of proteins produced in diseases with tissue destruction.
A.1635	Total protein test system	1	A total protein test system is a device intended to measure total protein(s) in serum or plasma. Measurements obtained by this device are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders.
A.1640	Protein-bound iodine test system	1	A protein-bound iodine test system is a device intended to measure protein-bound iodine in serum. Measurements of protein-bound iodine obtained by this device are used in the diagnosis and treatment of thyroid disorders.

A.1645	Urinary protein or albumin (nonquantitative) test system	1	A urinary protein or albumin (nonquantitative) test system is a device intended to identify proteins or albumin in urine. Identification of urinary protein or albumin (nonquantitative) is used in the diagnosis and treatment of disease conditions such as renal or heart diseases or thyroid disorders, which are characterized by proteinuria or albuminuria.
A.1650	Pyruvate kinase test system	1	A pyruvate kinase test system is a device intended to measure the activity of the enzyme pyruvate kinase in erythrocytes (red blood cells). Measurements obtained by this device are used in the diagnosis and treatment of various inherited anemias due to pyruvate kinase deficiency or of acute leukemias.
A.1655	Pyruvic acid test system	1	A pyruvic acid test system is a device intended to measure pyruvic acid (an intermediate compound in the metabolism of carbohydrate) in plasma. Measurements obtained by this device are used in the evaluation of electrolyte metabolism and in the diagnosis and treatment of acid-base and electrolyte disturbances or anoxia (the reduction of oxygen in body tissues).
A.1660	Quality control material (assayed and unassayed)	1,2	(a) Identification: A quality control material (assayed and unassayed) for clinical chemistry is a device intended for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation. A quality control material (assayed and unassayed) may be used for proficiency testing in interlaboratory surveys. This generic type of device includes controls (assayed and unassayed) for blood gases, electrolytes, enzymes, multianalytes (all kinds), single (specified) analytes, or urinalysis controls. (b) Classification: (1) Class 1: The device is not made from serum of human or animal origin, or is used for proficiency testing in interlaboratory surveys. (2) Class 2: The device is made from serum of human or animal origin, or is used for drug abuse detection.
A.1665	Sodium test system	2	A sodium test system is a device intended to measure sodium in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.
A.1670	Sorbitol dehydrogenase test system	1	A sorbitol dehydrogenase test system is a device intended to measure the activity of the enzyme sorbitol dehydrogenase in serum. Measurements obtained by this device are used in the diagnosis and treatment of liver disorders such as cirrhosis or acute hepatitis.

A.1675	Blood specimen collection device	2	A blood specimen collection device is a device intended for medical purposes to collect and to handle blood specimens and to separate serum from nonserum (cellular) components prior to further testing. This generic type device may include blood collection tubes, vials, systems, serum separators, blood collection trays, or vacuum sample tubes.
A.1678	Tacrolimus test system	2	A tacrolimus test system is a device intended to quantitatively determine tacrolimus concentrations as an aid in the management of transplant patients receiving therapy with this drug. This generic type of device includes immunoassays and chromatographic assays for tacrolimus.
A.1680	Testosterone test system	1	A testosterone test system is a device intended to measure testosterone (a male sex hormone) in serum, plasma, and urine. Measurement of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.
A.1685	Thyroxine-binding globulin test system	2	A thyroxine-binding globulin test system is a device intended to measure thyroxine (thyroid)-binding globulin (TBG), a plasma protein which binds thyroxine, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.
A.1690	Thyroid stimulating hormone test system	2	A thyroid stimulating hormone test system is a device intended to measure thyroid stimulating hormone, also known as thyrotrophin and thyrotrophic hormone, in serum and plasma. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.
A.1695	Free thyroxine test system	2	A free thyroxine test system is a device intended to measure free (not protein bound) thyroxine (thyroid hormone) in serum or plasma. Levels of free thyroxine in plasma are thought to reflect the amount of thyroxine hormone available to the cells and may therefore determine the clinical metabolic status of thyroxine. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.
A.1700	Total thyroxine test system	2	A total thyroxine test system is a device intended to measure total (free and protein bound) thyroxine (thyroid hormone) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.
A.1705	Triglyceride test system	1	A triglyceride test system is a device intended to measure triglyceride (neutral fat) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.
A.1710	Total triiodothyronine test system	1	A total triiodothyronine test system is a device intended to measure the hormone triiodothyronine in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases such as hyperthyroidism.

A.1715	Triiodothyronine uptake test system	1	A triiodothyronine uptake test system is a device intended to measure the total amount of binding sites available for binding thyroid hormone on the thyroxine-binding proteins, thyroid-binding globulin, thyroxine-binding prealbumin, and albumin of serum and plasma. The device provides an indirect measurement of thyrkoxine levels in serum and plasma. Measurements of triiodothyronine uptake are used in the diagnosis and treatment of thyroid disorders.
A.1720	Triose phosphate isomerase test system	1	A triose phosphate isomerase test system is a device intended to measure the activity of the enzyme triose phosphate isomerase in erythrocytes (red blood cells). Triose phosphate isomerase is an enzyme important in glycolysis (the energy-yielding conversion of glucose to lactic acid in various tissues). Measurements obtained by this device are used in the diagnosis and treatment of congenital triose phosphate isomerase enzyme deficiency, which causes a type of hemolytic anemia.
A.1725	Trypsin test system	1	A trypsin test system is a device intended to measure the activity of trypsin (a pancreatic enzyme important in digestion for the breakdown of proteins) in blood and other body fluids and in feces. Measurements obtained by this device are used in the diagnosis and treatment of pancreatic disease.
A.1730	Free tyrosine test system	1	A free tyrosine test system is a device intended to measure free tyrosine (an amono acid) in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of diseases such as congenital tyrosinemia (a disease that can cause liver/kidney disorders) and as an adjunct to the measurement of phenylalanine in detecting congenital phenylketonuria (a disease that can cause brain damage).
A.1770	Urea nitrogen test system	2	A urea nitrogen test system is a device intended to measure urea nitrogen (an end-product of nitrogen metabolism) in whole blood, serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.
A.1775	Uric acid test system	1	A uric acid test system is a device intended to measure uric acid in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.
A.1780	Urinary calculi (stones) test system	1	A urinary calculi (stones) test system is a device intended for the analysis of urinary calculi. Analysis of urinary calculi is used in the diagnosis and treatment of calculi of the urinary tract.
A.1785	Urinary urobilinogen (nonquantitative) test system	1	A urinary urobilinogen (nonquantitative) test system is a device intended to detect and estimate urobilinogen (a bile pigment degradation product of red cell hemoglobin) in urine. Estimations obtained by this device are used in the diagnosis and treatment of liver diseases and hemolytic (red cells) disorders.

A.1790	Uroporphyrin test system	1	A uroporphyrin test system is a device intended to measure uroporphyrin in urine. Measurements obtained by this device are used in the diagnosis and treatment of porphyrias (primarily inherited diseases associated with disturbed porphyrin metabolism), lead poisoning, and other diseases characterized by alterations in the heme pathway.
A.1795	Vanilmandelic acid test system	1	A vanilmandelic acid test system is a device intended to measure vanilmandelic acid in urine. Measurements of vanilmandelic acid obtained by this device are used in the diagnosis and treatment of neuroblastoma, pheochromocytoma, and certain hypertensive conditions.
A.1805	Vitamin A test system	1	A vitamin A test system is a device intended to measure vitamin A in serum or plasma. Measurements obtained by this device are used in the diagnosis and treatment of vitamin A deficiency conditions, including night blindness, or skin, eye, or intestinal disorders.
A.1810	Vitamin B12 test system	2	A vitamin B12test system is a device intended to measure vitamin B12in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.
A.1815	Vitamin E test system	1	A vitamin E test system is a device intended to measure vitamin E (tocopherol) in serum. Measurements obtained by this device are used in the diagnosis and treatment of infants with vitamin E deficiency syndrome.
A.1820	Xylose test system	1	A xylose test system is a device intended to measure xylose (a sugar) in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of gastrointestinal malabsorption syndrome (a group of disorders in which there is subnormal absorption of dietary constituents and thus excessive loss from the body of the nonabsorbed substances).
A.1825	Vitamin D test system	2	A vitamin D test system is a device intended for use in clinical laboratories for the quantitative determination of 25-hydroxyvitamin D (25-OH-D) and other hydroxylated metabolites of vitamin D in serum or plasma to be used in the assessment of vitamin D sufficiency.
A.1840	Total 25-hydroxyvitamin D mass spectrometry test system	2	A total 25-hydroxyvitamin D mass spectrometry test system is a device intended for use in clinical laboratories for the quantitative determination of total 25-hydroxyvitamin D (25-OH-D) in serum or plasma to be used in the assessment of vitamin D sufficiency.
A.2140	Centrifugal chemistry analyzer for clinical use	1	A centrifugal chemistry analyzer for clinical use is an automatic device intended to centrifugally mix a sample and a reagent and spectrophotometrically measure concentrations of the sample constituents. This device is intended for use in conjunction with certain materials to measure a variety of analytes.
A.2150	Continuous flow sequential multiple chemistry analyzer for clinical use	1	A continuous flow sequential multiple chemistry analyzer for clinical use is a modular analytical instrument intended to simultaneously perform multiple chemical procedures using the principles of automated continuous flow systems. This device is intended for use in conjunction with certain materials to measure a variety of analytes.

A.2160	Discrete photometric chemistry analyzer for clinical use	1	A discrete photometric chemistry analyzer for clinical use is a device intended to duplicate manual analytical procedures by performing automatically various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes. Different models of the device incorporate various instrumentation such as micro analysis apparatus, double beam, single, or dual channel photometers, and bichromatic 2-wavelength photometers. Some models of the device may include reagent-containing components that may also serve as reaction units.
A.2170	Micro chemistry analyzer for clinical use	1	A micro chemistry analyzer for clinical use is a device intended to duplicate manual analytical procedures by performing automatically various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. The distinguishing characteristic of the device is that it requires only micro volume samples obtainable from pediatric patients. This device is intended for use in conjunction with certain materials to measure a variety of analytes.
A.2250	Gas liquid chromatography system for clinical use	1	A gas liquid chromatography system for clinical use is a device intended to separate one or more drugs or compounds from a mixture. Each of the constituents in a vaporized mixture of compounds is separated according to its vapor pressure. The device may include accessories such as columns, gases, column supports, and liquid coating.
A.2260	High pressure liquid chromatography system for clinical use	1	A high pressure liquid chromatography system for clinical use is a device intended to separate one or more drugs or compounds from a solution by processing the mixture of compounds (solutes) through a column packed with materials of uniform size (stationary phase) under the influence of a high pressure liquid (mobile phase). Separation of the solutes occurs either by absorption, sieving, partition, or selective affinity.
A.2265	High throughput genomic sequence analyzer	2	A high throughput genomic sequence analyzer for clinical use is an analytical instrument system intended to generate, measure and sort signals in order to analyze nucleic acid sequences in a clinical sample. The device may include a signal reader unit; reagent handling, dedicated instrument control, and other hardware components; raw data storage mechanisms; data acquisition software; and software to process detected signals.
A.2270	Thin-layer chromatography system for clinical use	1	A thin-layer chromatography (TLC) system for clinical use is a device intended to separate one or more drugs or compounds from a mixture. The mixture of compounds is absorbed onto a stationary phase or thin layer of inert material (e.g., cellulose, alumina, etc.) and eluted off by a moving solvent (moving phase) until equilibrium occurs between the two phases.
A.2300	Colorimeter, photometer, or spectrophotometer for clinical use	1	A colorimeter, a photometer, or a spectrophotometer for clinical use is an instrument intended to measure radiant energy emitted, transmitted, absorbed, or reflected under controlled conditions. The device may include a monochromator to produce light of a specific wavelength.

A.2320	Beta or gamma counter for clinical use	1	A beta or gamma counter for clinical use is a device intended to detect and count beta or gamma radiation emitted by clinical samples. Clinical samples are prepared by addition of a radioactive reagent to the sample. These measurements are useful in the diagnosis and treatment of various disorders.
A.2400	Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use	1	A densitometer/scanner (integrating, reflectance, thin-layer chromatography, or radiochromatogram) for clinical use is device intended to measure the concentration of a substance on the surface of a film or other support media by either a photocell measurement of the light transmission through a given area of the medium or, in the case of the radiochromatogram scanner, by measurement of the distribution of a specific radio-active element on a radiochromatogram.
A.2485	Electrophoresis apparatus for clinical use	1	An electrophoresis apparatus for clinical use is a device intended to separate molecules or particles, including plasma proteins, lipoproteins, enzymes, and hemoglobulins on the basis of their net charge in specified buffered media. This device is used in conjunction with certain materials to measure a variety of analytes as an aid in the diagnosis and treatment of certain disorders.
A.2500	Enzyme analyzer for clinical use	1	An enzyme analyzer for clinical use is a device intended to measure enzymes in plasma or serum by nonkinetic or kinetic measurement of enzyme-catalyzed reactions. This device is used in conjunction with certain materials to measure a variety of enzymes as an aid in the diagnosis and treatment of certain enzyme-related disorders.
A.2540	Flame emission photometer for clinical use	1	A flame emission photometer for clinical use is a device intended to measure the concentration of sodium, potassium, lithium, and other metal ions in body fluids. Abnormal variations in the concentration of these substances in the body are indicative of certain disorders (e.g., electrolyte imbalance and heavy metal intoxication) and are, therefore, useful in diagnosis and treatment of those disorders.
A.2560	Fluorometer for clinical use	1	A fluorometer for clinical use is a device intended to measure by fluorescence certain analytes. Fluorescence is the property of certain substances of radiating, when illuminated, a light of a different wavelength. This device is used in conjunction with certain materials to measure a variety of analytes.
A.2570	Instrumentation for clinical multiplex test systems.	2	Instrumentation for clinical multiplex test systems is a device intended to measure and sort multiple signals generated by an assay from a clinical sample. This instrumentation is used with a specific assay to measure multiple similar analytes that establish a single indicator to aid in diagnosis. Such instrumentation may be compatible with more than one specific assay. The device includes a signal reader unit, and may also integrate reagent handling, hybridization, washing, dedicated instrument control, and other hardware components, as well as raw data storage mechanisms, data acquisition software, and software to process detected signals.
A.2700	Nephelometer for clinical use	1	A nephelometer for clinical use is a device intended to estimate the concentration of particles in a suspension by measuring their light scattering properties (the deflection of light rays by opaque particles in their path). The device is used in conjunction with certain materials to measure the concentration of a variety of analytes.

A.2720	Plasma oncometer for clinical use	1	A plasma oncometer for clinical use is a device intended to measure plasma oncotic pressure, which is that portion of the total plasma osmotic pressure contributed by protein and other molecules too large to pass through a specified semipermeable membrane. Because variations in plasma oncotic pressure are indications of certain disorders, measurements of the variations are useful in the diagnosis and treatment of these disorders.
A.2730	Osmometer for clinical use	1	An osmometer for clinical use is a device intended to measure the osmotic pressure of body fluids. Osmotic pressure is the pressure required to prevent the passage of a solution with a lesser solute concentration into a solution with greater solute concentration when the two solutions are separated by a semipermeable membrane. The concentration of a solution affects its osmotic pressure, freezing point, and other physiochemical properties. Osmometers determine osmotic pressure by methods such as the measurement of the freezing point. Measurements obtained by this device are used in the diagnosis and treatment of body fluid disorders.
A.2800	Refractometer for clinical use	1	A refractometer for clinical use is a device intended to determine the amount of solute in a solution by measuring the index of refraction (the ratio of the velocity of light in a vacuum to the velocity of light in the solution). The index of refraction is used to measure the concentration of certain analytes (solutes), such a plasma total proteins and urinary total solids. Measurements obtained by this device are used in the diagnosis and treatment of certain conditions.
A.2850	Atomic absorption spectrophotometer for clinical use	1	An atomic absorption spectrophotometer for clinical use is a device intended to identify and measure elements and metals (e.g., lead and mercury) in human specimens. The metal elements are identified according to the wavelength and intensity of the light that is absorbed when the specimen is converted to the atomic vapor phase. Measurements obtained by this device are used in the diagnosis and treatment of certain conditions.
A.2860	Mass spectrometer for clinical use	1	A mass spectrometer for clinical use is a device intended to identify inorganic or organic compounds (e.g., lead, mercury, and drugs) in human specimens by ionizing the compound under investigation and separating the resulting ions by means of an electrical and magnetic field according to their mass.
A.2900	Automated urinalysis system	1	An automated urinalysis system is a device intended to measure certain of the physical properties and chemical constituents of urine by procedures that duplicate manual urinalysis systems. This device is used in conjunction with certain materials to measure a variety of urinary analytes.
A.2920	Plasma viscometer for clinical use	1	A plasma viscometer for clinical use is a device intended to measure the viscosity of plasma by determining the time period required for the plasma to flow a measured distance through a calibrated glass tube. Measurements obtained by this device are used to monitor changes in the amount of solids present in plasma in various disorders.
A.3030	Acetaminophen tests system	2	An acetaminophen test system is a device intended to measure acetaminophen, an analgestic and fever reducing drug, in serum. Measurements obtained by this device are used in the diagnosis and treatment of acetaminophen overdose.

A.3035	Amikacin test system	2	An amikacin test system is a device intended to measure amikacin, an aminoglycoside antibiotic drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of amikacin overdose and in monitoring levels of amikacin to ensure appropriate therapy.
A.3040	Alcohol test system	2	An alcohol test system is a device intented to measure alcohol (e.g., ethanol, methanol, isopropanol, etc.) in human body fluids (e.g., serum, whole blood, and urine). Measurements obtained by this device are used in the diagnosis and treatment of alcohol intoxication and poisoning.
A.3050	Breath-alcohol test system	1	A breath-alcohol test system is a device intened to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.
A.3080	Breath nitric oxide test system	2	A breath nitric oxide test system is a device intended to measure fractional nitric oxide in human breath. Measurement of changes in fractional nitric oxide concentration in expired breath aids in evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to established clinical and laboratory assessments of asthma. A breath nitric oxide test system combines chemiluminescence detection of nitric oxide with a pneumotachograph, display, and dedicated software.
A.3100	Amphetamine test system	2	An amphetamine test system is a device intended to measure amphetamine, a central nervous system stimulating drug, in plasma and urine. Measurements obtained by this device are used in the diagnosis and treatment of amphetamine use or overdose and in monitoring levels of amphetamine to ensure appropriate therapy.
A.3110	Antimony test system	1	An antimony test system is a device intended to measure antimony, a heavy metal, in urine, blood, vomitus, and stomach contents. Measurements obtained by this device are used in the diagnosis and treatment of antimony poisoning.
A.3120	Arsenic test system	1	An arsenic test system is a device intended to measure arsenic, a poisonous heavy metal, in urine, vomitus, stomach contents, nails, hair, and blood. Measurements obtained by this device are used in the diagnosis and treatment of arsenic poisoning.
A.3150	Barbiturate test system	2	A barbiturate test system is a device intended to measure barbiturates, a class of hypnotic and sedative drugs, in serum, urine, and gastric contents. Measurements obtained by this device are used in the diagnosis and treatment of barbiturate use or overdose and in monitoring levels of barbiturate to ensure appropriate therapy.
A.3170	Benzodiazepine test system	2	A benzodiazepine test system is a device intended to measure any of the benzodiazepine compounds, sedative and hypnotic drugs, in blood, plasma, and urine. The benzodiazepine compounds include chlordiazepoxide, diazepam, oxazepam, chlorzepate, flurazepam, and nitrazepam. Measurements obtained by this device are used in the diagnosis and treatment of benzodiazepine use or overdose and in monitoring levels of benzodiazepines to ensure appropriate therapy.

A.3200	Clinical toxicology calibrator	2	A clinical toxicology calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens. A clinical toxicology calibrator can be a mixture of drugs or a specific material for a particular drug (e.g., ethanol, lidocaine, etc.).
A.3220	Carbon monoxide test system	1	A carbon monoxide test system is a device intended to measure carbon monoxide or carboxyhemoglobin (carbon monoxide bound to the hemoglobin in the blood) in blood. Measurements obtained by this device are used in the diagnosis and treatment of or confirmation of carbon monoxide poisoning.
A.3240	Cholinesterase test system	1	A cholinesterase test system is a device intended to measure cholinesterase (an enzyme that catalyzes the hydrolysis of acetylcholine to choline) in human specimens. There are two principal types of cholinesterase in human tissues. True cholinesterase is present at nerve endings and in erythrocytes (red blood cells) but is not present in plasma. Pseudo cholinesterase is present in plasma and liver but is not present in erythrocytes. Measurements obtained by this device are used in the diagnosis and treatment of cholinesterase inhibition disorders (e.g., insecticide poisoning and succinylcholine poisoning).
A.3250	Cocaine and cocaine metabolite test system	2	A cocaine and cocaine metabolite test system is a device intended to measure cocaine and a cocaine metabolite (benzoylecgonine) in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of cocaine use or overdose.
A.3270	Codeine test system	2	A codeine test system is a device intended to measure codeine (a narcotic pain-relieving drug) in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of codeine use or overdose and in monitoring levels of codeine to ensure appropriate therapy.
A.3300	Digitoxin test system	2	A digitoxin test system is a device intended to measure digitoxin, a cardiovascular drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of digitoxin overdose and in monitoring levels of digitoxin to ensure appropriate therapy.
A.3320	Digoxin test system	2	A digoxin test system is a device intended to measure digoxin, a cardiovascular drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.
A.3350	Diphenylhydantoin test system	2	A diphenylhydantoin test system is a device intended to measure diphenylhydantoin, an antiepileptic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of diphenylhydantoin overdose and in monitoring levels of diphenylhydantoin to ensure appropriate therapy.

A.3360	Drug metabolizing enzyme genotyping system.	2	A drug metabolizing enzyme genotyping system is a device intended for use in testing deoxyribonucleic acid (DNA) extracted from clinical samples to identify the presence or absence of human genotypic markers encoding a drug metabolizing enzyme. This device is used as an aid in determining treatment choice and individualizing treatment dose for therapeutics that are metabolized primarily by the specific enzyme about which the system provides genotypic information.
A.3380	Ethosuximide test system	2	An ethosuximide test system is a device intended to measure ethosuximide, an antiepileptic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of ethosuximide overdose and in monitoring levels of ethosuximide to ensure appropriate therapy.
A.3450	Gentamicin test system	2	A gentamicin test system is a device intended to measure gentamicin, an antibiotic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to ensure appropriate therapy.
A.3520	Kanamycin test system	2	A kanamycin test system is a device intended to measure kanamycin, an antibiotic drug, in plasma and serum. Measurements obtained by this device are used in the diagnosis and treatment of kanamycin overdose and in monitoring levels of kanamycin to ensure appropriate therapy.
A.3550	Lead test system	2	A lead test system is a device intended to measure lead, a heavy metal, in blood and urine. Measurements obtained by this device are used in the diagnosis and treatment of lead poisoning.
A.3555	Lidocaine test system	2	A lidocaine test system is a device intended to measure lidocaine, an antiarrythmic and anticonvulsant drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of lidocaine overdose or in monitoring levels of lidocaine to ensure appropriate therapy.
A.3560	Lithium test system	2	A lithium test system is a device intended to measure lithium (from the drug lithium carbonate) in serum or plasma. Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).
A.3580	Lysergic acid diethylamide (LSD) test system	2	A lysergic acid diethylamide (LSD) test system is a device intended to measure lysergic acid diethylamide, a hallucinogenic drug, in serum, urine, and gastric contents. Measurements obtained by this device are used in the diagnosis and treatment of LSD use or overdose.
A.3590	Meprobamate test system	2	A meprobamate test system is a device intended to measure meprobamate in human specimens. Measurements obtained by this device are used to detect the presence of meprobamate to diagnose the use or overdose of meprobamate or structurally-related drug compounds (e.g., prodrugs).
A.3600	Mercury test system	1	A mercury test system is a device intended to measure mercury, a heavy metal, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of mercury poisoning.

A.3610	Methamphetamine test system	2	A methamphetamine test system is a device intended to measure methamphetamine, a central nervous system stimulating drug, in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of methamphetamine use or overdose.
A.3620	Methadone test system	2	A methadone test system is a device intended to measure methadone, an addictive narcotic pain-relieving drug, in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of methadone use or overdose and to determine compliance with regulations in methadone maintenance treatment.
A.3630	Methaqualone test system	2	A methaqualone test system is a device intended to measure methaqualone, a hypnotic and sedative drug, in urine. Measurements obtained by this device are used in the diagnosis and treatment of methaqualone use or overdose.
A.3640	Morphine test system	2	A morphine test system is a device intended to measure morphine, an addictive narcotic pain-relieving drug, and its analogs in serum, urine, and gastric contents. Measurements obtained by this device are used in the diagnosis and treatment of morphine use or overdose and in monitoring levels of morphine and its analogs to ensure appropriate therapy.
A.3645	Neuroleptic drugs radioreceptor assay test system	2	A neuroleptic drugs radioceptor assay test system is a device intended to measure in serum or plasma the dopamine receptor blocking activity of neuroleptic drugs and their active metabolites. A neuroleptic drug has anti-psychotic action affecting principally psychomotor activity, is generally without hypnotic effects, and is a tranquilizer. Measurements obtained by this device are used to aid in determining whether a patient is taking the prescribed dosage level of such drugs.
A.3650	Opiate test system	2	An opiate test system is a device intended to measure any of the addictive narcotic pain-relieving opiate drugs in blood, serum, urine, gastric contents, and saliva. An opiate is any natural or synthetic drug that has morphine-like pharmocological actions. The opiates include drugs such as morphine, morphine glucoronide, heroin, codeine, nalorphine, and meperedine. Measurements obtained by this device are used in the diagnosis and treatment of opiate use or overdose and in monitoring the levels of opiate administration to ensure appropriate therapy.
A.3652	Organophosphate test system	2	An organophosphate test system is a device intended to measure organophosphate metabolites quantitatively in human urine from individuals who have signs and symptoms consistent with cholinesterase poisoning. The data obtained by this device is intended to aid in the confirmation and investigation of organophosphate exposure.
A.3660	Phenobarbital test system	2	A phenobarbitol test system is a device intended to measure phenobarbital, an antiepileptic and sedative-hypnotic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of phenobarbital use or overdose and in monitoring levels of phenobarbital to ensure appropriate therapy.
A.3670	Phenothiazine test system	2	A phenothiazine test system is a device intended to measure any of the drugs of the phenothiazine class in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of phenothiazine use or overdose.

A.3680	Primidone test system	2	A primidone test system is a device intended to measure primidone, an antiepileptic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of primidone overdose and in monitoring levels of primidone to ensure appropriate therapy.
A.3700	Propoxyphene test system	2	A propoxyphene test system is a device intended to measure propoxyphene, a pain-relieving drug, in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of propoxyphene use or overdose or in monitoring levels of propoxyphene to ensure appropriate therapy.
A.3750	Quinine test system	1	A quinine test system is a device intended to measure quinine, a fever-reducing and pain-relieving drug intended in the treatment of malaria, in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of quinine overdose and malaria.
A.3830	Salicylate test system	2	A salicylate test system is a device intended to measure salicylates, a class of analgesic, antipyretic and anti-inflammatory drugs that includes aspirin, in human specimens. Measurements obtained by this device are used in diagnosis and treatment of salicylate overdose and in monitoring salicylate levels to ensure appropriate therapy.
A.3840	Sirolimus test system.	2	A sirolimus test system is a device intended to quantitatively determine sirolimus concentrations in whole blood. Measurements are used as an aid in management of transplant patients receiving therapy with sirolimus.
A.3850	Sulfonamide test system	1	A sulfonamide test system is a device intended to measure sulfonamides, any of the antibacterial drugs derived from sulfanilamide, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of sulfonamide overdose and in monitoring sulfonamide levels to ensure appropriate therapy.
A.3870	Cannabinoid test system	2	A cannabinoid test system is a device intended to measure any of the cannabinoids, hallucinogenic compounds endogenous to marihuana, in serum, plasma, saliva, and urine. Cannabinoid compounds includedelta -9-tetrahydrocannabinol, cannabidiol, cannabinol, and cannabichromene. Measurements obtained by this device are used in the diagnosis and treatment of cannabinoid use or abuse and in monitoring levels of cannabinoids during clinical investigational use.
A.3880	Theophylline test system	2	A theophylline test system is a device intended to measure theophylline (a drug used for stimulation of the muscles in the cardiovascular, respiratory, and central nervous systems) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of theophylline overdose or in monitoring levels of theophylline to ensure appropriate therapy.
A.3900	Tobramycin test system	2	A tobramycin test system is a device intended to measure tobramycin, an aminoglycoside antibiotic drug, in plasma and serum. Measurements obtained by this device are used in the diagnosis and treatment of tobramycin overdose and in monitoring levels of tobramycin to ensure appropriate therapy.

A.3910	Tricyclic antidepressant drugs test system	2	A tricyclic antidepressant drugs test system is a device intended to measure any of the tricyclic antidepressant drugs in serum. The tricyclic antidepressant drugs include imipramine, desipramine, amitriptyline, nortriptyline, protriptyline, and doxepin. Measurements obtained by this device are used in the diagnosis and treatment of chronic depression to ensure appropriate therapy.
A.3950	Vancomycin test system	2	A vancomycin test system is a device intended to measure vancomycin, an antibiotic drug, in serum. Measurements obtained by this device are used in the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy.
A.9999	Others(Clinical Chemistry and Clinical Toxicology Devices)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.
B.0001	Human leukocyte antigen typing system	2	Human leukocyte antigen typing system is a device for human leukocyte antigen identification and typing.
B.0002	Blood component extractor	1,2	Blood component extractor is a device to separate blood components from centrifuged whole blood. Classification: (1) Automatic blood component extractors including sensors, weighting devices, are Class 2 devices; (2) Other devices are Class 1 devices.
B.1850	Dye and chemical solution stains	1	Dye and chemical solution stains for medical purposes are mixtures of synthetic or natural dyes or nondye chemicals in solutions used in staining cells and tissues for diagnostic histopathology, cytopathology, or hematology.
B.1860	Immunohistochemistry reagents and kits	1,2, 3	Immunohistochemistry test systems (IHC's) are in vitro diagnostic devices consisting of polyclonal or monoclonal antibodies labeled with directions for use and performance claims, which may be packaged with ancillary reagents in kits. Their intended use is to identify, by immunological techniques, antigens in tissues or cytologic specimens. Similar devices intended for use with flow cytometry devices are not considered IHC's. Classification: (1)Class 1 devices used after the primary diagnosis of tumor (neoplasm) has been made by conventional histopathology using nonimmunologic histochemical stains, such as hematoxylin and eosin. Examples of class I IHC's are differentiation markers that are used as adjunctive tests to subclassify tumors, such as keratin. (2)Class 2 devices intended for the detection and/or measurement of certain target analytes in order to provide prognostic or predictive data that are not directly confirmed by routine histopathologic internal and external control specimens. These IHC's provide the pathologist with information that is ordinarily reported as independent diagnostic information to the ordering clinician, and the claims associated with these data are widely accepted and supported by valid scientific evidence. Examples of class 2 IHC's are those intended for semiquantitative measurement of an analyte, such as hormone receptors in breast cancer. (3) Class 3 devices intended for any use not described in paragraphs (1) or (2) of this section.

B.1865	Cervical intraepithelial neoplasia (CIN) test system	2	A cervical intraepithelial neoplasia (CIN) test system is a device used to detect a biomarker associated with CIN in human tissues. The device is indicated as an adjunct test and not to be used as a stand-alone device. The test results must be interpreted in the context of the patient's clinical history including, but not limited to, prior and current cervical biopsy results, Papanicolaou (Pap) test results, human papillomavirus (HPV) test results, and morphology on hematoxylin and eosin (H&E) stained sections. This device is not intended to detect the presence of HPV.
B.1866	Lynch Syndrome (LS) test systems	2	Lynch syndrome test systems are in vitro diagnostic tests for use with tumor tissue to identify previously diagnosed cancer patients at risk for having Lynch syndrome.
B.1870	Early Growth Response 1 (EGR1) gene Fluorescence In-situ Hybridization (FISH) test system	2	An early growth response 1 (EGR1) gene fluorescence in-situ hybridization (FISH) test system for specimen characterization is a device intended to detect the EGR1 probe target on chromosome 5q in bone marrow specimens from patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). The assay results are intended to be interpreted only by a qualified pathologist or cytogeneticist. These devices do not include automated systems that directly report results without review and interpretation by a qualified pathologist or cytogeneticist. These devices also do not include any device intended for use to select patient therapy, predict patient response to therapy, or to screen for disease as well as any device with a claim for a particular diagnosis, prognosis, monitoring, or risk assessment.
B.2220	Synthetic cell and tissue culture media and components	1	Synthetic cell and tissue culture media and components are substances that are composed entirely of defined components (e.g., amino acids, vitamins, inorganic salts) that are essential for the survival and development of cell lines of humans and other animals. This does not include tissue culture media for human ex vivo tissue and cell culture processing applications as described in 876.5885 of this chapter.
B.2260	Chromosome culture kit	1	A chromosome culture kit is a device containing the necessary ingredients (e.g., Minimum Essential Media (MEM) of McCoy's 5A culture media, phytohemagglutinin, fetal calf serum, antibiotics, and heparin) used to culture tissues for diagnosis of congenital chromosome abnormalities.
B.2280	Cultured animal and human cells	1	Cultured animal and human cells are in vitro cultivated cell lines from the tissue of humans or other animals which are used in various diagnostic procedures, particularly diagnostic virology and cytogenetic studies.
B.2360	Mycoplasma detection media and components	1	Mycoplasma detection media and components are used to detect and isolate mycoplasma pleuropneumonia-like organisms (PPLO), a common microbial contaminant in cell cultures.
B.2875	Balanced salt solutions or formulations	1	A balanced salt solution or formulation is a defined mixture of salts and glucose in a simple medium. This device is included as a necessary component of most cell culture systems. This media component controls for pH, osmotic pressure, energy source, and inorganic ions.

B.3700	Whole slide imaging system	2	The whole slide imaging system is an automated digital slide creation, viewing, and management system intended as an aid to the pathologist to review and interpret digital images of surgical pathology slides. The system generates digital images that would otherwise be appropriate for manual visualization by conventional light microscopy.
B.4020	Analyte specific reagents	1,2,3	Analyte specific reagents (ASR's) are antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reaction with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens. ASR's that otherwise fall within this definition are not within the scope when they are sold to:(1) In vitro diagnostic manufacturers; or(2) Organizations that use the reagents to make tests for purposes other than providing diagnostic information to patients and practitioners, e.g., forensic, academic, research, and other nonclinical laboratories. Classification: (1) Class 1;(2) Class 2 devices used in blood banking tests;(3) Class 3 (i) The analyte is intended as a component in a test intended for use in the diagnosis of a contagious condition that is highly likely to result in a fatal outcome and prompt, accurate diagnosis offers the opportunity to mitigate the public health impact of the condition (e.g., human immunodeficiency virus (HIV/AIDS)or tuberculosis (TB)); or (ii) The analyte is intended as a component in a test intended for use in donor screening for conditions for which TFDA has recommended or required testing in order to safeguard the blood supply or establish the safe use of blood and blood products (e.g., tests for hepatitis or tests for identifying blood groups).Devices for the following intended use should refer to other TFDA regulations including. (a) Devices intended to use in the diagnosis of a contagious condition that is highly likely to result in a fatal outcome and prompt, accurate diagnosis offers the opportunity to miti- gate the public health.(b) devices intended as a component in a test intended for use in donor screening for conditions for which TFDA has recommended or required testing in order to safeguard the blood supply or establish the safe use of blood and blood products.
B.4400	Enzyme preparations	1	Enzyme preparations are products that are used in the histopathology laboratory for the following purposes: (1) To disaggregate tissues and cells already in established cultures for preparation into subsequent cultures (e.g., trypsin);(2) To disaggregate fluid specimens for cytological examination (e.g., papain for gastric lavage or trypsin for sputum liquefaction);(3) To aid in the selective staining of tissue specimens (e.g., diastase for glycogen determination).

B.5200	Automated cell counter	2	An automated cell counter is a fully-automated or semi-automated device used to count red blood cells, white blood cells, or blood platelets using a sample of the patient's peripheral blood (blood circulating in one of the body's extremities, such as the arm). These devices may also measure hemoglobin or hematocrit and may also calculate or measure one or more of the red cell indices (the erythrocyte mean corpuscular volume, the mean corpuscular hemoglobin, or the mean corpuscular hemoglobin concentration). These devices may use either an electronic particle counting method or an optical counting method.
B.5220	Automated differential cell counter	2	An automated differential cell counter is a device used to identify one or more of the formed elements of the blood. The device may also have the capability to flag, count, or classify immature or abnormal hematopoietic cells of the blood, bone marrow, or other body fluids. These devices may combine an electronic particle counting method, optical method, or a flow cytometric method utilizing monoclonal CD (cluster designation) markers. The device includes accessory CD markers.
B.5240	Automated blood cell diluting apparatus	1	An automated blood cell diluting apparatus is a fully automated or semi-automated device used to make appropriate dilutions of a blood sample for further testing.
B.5260	Automated cell-locating device	2	An automated cell-locating device is a device used to locate blood cells on a peripheral blood smear, allowing the operator to identify and classify each cell according to type. (Peripheral blood is blood circulating in one of the body's extremities, such as the arm.)
B.5300	Red cell indices device	2	A red cell indices device, usually part of a larger system, calculates or directly measures the erythrocyte mean corpuscular volume (MCV), the mean corpuscular hemoglobin (MCH), and the mean corpuscular hemoglobin concentration (MCHC). The red cell indices are used for the differential diagnosis of anemias.
B.5350	Microsedimentation centrifuge	1	A microsedimentation centrifuge is a device used to sediment red cells for the microsedimentation rate test.
B.5400	Coagulation instrument	2	A coagulation instrument is an automated or semiautomated device used to determine the onset of clot formation for in vitro coagulation studies.
B.5425	Multipurpose system for in vitro coagulation studies	2	A multipurpose system for in vitro coagulation studies is a device consisting of one automated or semiautomated instrument and its associated reagents and controls. The system is used to perform a series of coagulation studies and coagulation factor assays.
B.5600	Automated hematocrit instrument	2	An automated hematocrit instrument is a fully automated or semi-automated device which may or may not be part of a larger system. This device measures the packed red cell volume of a blood sample to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red cells).
B.5620	Automated hemoglobin system	2	An automated hemoglobin system is a fully automated or semi-automated device which may or may not be part of a larger system. The generic type of device consists of the reagents, calibrators, controls, and instrumentation used to determine the hemoglobin content of human blood.

B.5680	Automated heparin analyzer	2	An automated heparin analyzer is a device used to determine the heparin level in a blood sample by mixing the sample with protamine (a heparin-neutralizing substance) and determining photometrically the onset of air-activated clotting. The analyzer also determines the amount of protamine necessary to neutralize the heparin in the patient's circulation.
B.5700	Automated platelet aggregation system	2	An automated platelet aggregation system is a device used to determine changes in platelet shape and platelet aggregation following the addition of an aggregating reagent to a platelet-rich plasma.
B.5800	Automated sedimentation rate device	1	An automated sedimentation rate device is an instrument that measures automatically the erythrocyte sedimentation rate in whole blood. Because an increased sedimentation rate indicates tissue damage or inflammation, the erythrocyte sedimentation rate device is useful in monitoring treatment of a disease.
B.5850	Automated slide spinner	1	An automated slide spinner is a device that prepares automatically a blood film on a microscope slide using a small amount of peripheral blood (blood circulating in one of the body's extremities, such as the arm).
B.5950	Blood volume measuring device	2	A blood volume measuring device is a manual, semiautomated, or automated system that is used to calculate the red cell mass, plasma volume, and total blood volume.
B.6100	Bleeding time device	1	A bleeding time device is a device, usually employing two spring-loaded blades, that produces two small incisions in the patient's skin. The length of time required for the bleeding to stop is a measure of the effectiveness of the coagulation system, primarily the platelets.
B.6150	Capillary blood collection tube	1	A capillary blood collection tube is a plain or heparinized glass tube of very small diameter used to collect blood by capillary action.
B.6160	Manual blood cell counting device	1	A manual blood cell counting device is a device used to count red blood cells, white blood cells, or blood platelets.
B.6400	Hematocrit measuring device	1	A hematocrit measuring device is a system consisting of instruments, tubes, racks, and a sealer and a holder. The device is used to measure the packed red cell volume in blood to determine whether the patient's total red cell volume is normal or abnormal. Abnormal states include anemia (an abnormally low total red cell volume) and erythrocytosis (an abnormally high total red cell mass). The packed red cell volume is produced by centrifuging a given volume of blood.
B.6550	Occult blood test	2	An occult blood test is a device used to detect occult blood in urine or feces. (Occult blood is blood present in such small quantities that it can be detected only by chemical tests of suspected material, or by microscopic or spectroscopic examination.)
B.6600	Osmotic fragility test	1	An osmotic fragility test is a device used to determine the resistance of red blood cells to hemolysis (destruction) in varying concentrations of hypotonic saline solutions.
B.6650	Platelet adhesion test	2	A platelet adhesion test is a device used to determine in vitro platelet function.

B.6675	Platelet aggregometer	2	A platelet aggregometer is a device, used to determine changes in platelet shape and platelet aggregation following the addition of an aggregating reagent to a platelet rich plasma.
B.6700	Erythrocyte sedimentation rate test	1	An erythrocyte sedimentation rate test is a device that measures the length of time required for the red cells in a blood sample to fall a specified distance or a device that measures the degree of sedimentation taking place in a given length of time. An increased rate indicates tissue damage or inflammation.
B.7010	Flow cytometric test for hematopoietic neoplasms	2	A flow cytometric test for hematopoietic neoplasms is a device that consists of reagents for immunophenotyping of human cells in relation to the level of expression, antigen density, and distribution of specific cellular markers. These reagents are used as an aid in the differential diagnosis or monitoring of hematologically abnormal patients having or suspected of having hematopoietic neoplasms. The results should be interpreted by a pathologist or equivalent professional in conjunction with other clinical and laboratory findings.
B.7040	Adenosine triphosphate release assay	1	An adenosine triphosphate release assay is a device that measures the release of adenosine triphosphate (ATP) from platelets following aggregation. This measurement is made on platelet-rich plasma using a photometer and a luminescent firefly extract. Simultaneous measurements of platelet aggregation and ATP release are used to evaluate platelet function disorders.
B.7060	Antithrombin III assay	2	An antithrombin III assay is a device that is used to determine the plasma level of antithrombin III (a substance which acts with the anticoagulant heparin to prevent coagulation). This determination is used to monitor the administration of heparin in the treatment of thrombosis. The determination may also be used in the diagnosis of thrombophilia (a congenital deficiency of antithrombin III).
B.7100	Red blood cell enzyme assay	2	Red blood cell enzyme assay is a device used to measure the activity in red blood cells of clinically important enzymatic reactions and their products, such as pyruvate kinase or 2,3-diphosphoglycerate. A red blood cell enzyme assay is used to determine the enzyme defects responsible for a patient's hereditary hemolytic anemia.
B.7140	Activated whole blood clotting time tests	2	An activated whole blood clotting time tests is a device, used to monitor heparin therapy for the treatment of venous thrombosis or pulmonary embolism by measuring the coagulation time of whole blood.
B.7250	Erythropoietin assay	2	A erythropoietin assay is a device that measures the concentration of erythropoietin (an enzyme that regulates the production of red blood cells) in serum or urine. This assay provides diagnostic information for the evaluation of erythrocytosis (increased total red cell mass) and anemia.
B.7275	Euglobulin lysis time tests	2	A euglobulin lysis time test is a device that measures the length of time required for the lysis (dissolution) of a clot formed from fibrinogen in the euglobulin fraction (that fraction of the plasma responsible for the formation of plasmin, a clot lysing enzyme). This test evaluates natural fibrinolysis (destruction of a blood clot after bleeding has been arrested). The test also will detect accelerated fibrinolysis.

B.7280	Factor V Leiden DNA mutation detection systems	2	Factor V Leiden deoxyribonucleic acid (DNA) mutation detection systems are devices that consist of different reagents and instruments which include polymerase chain reaction (PCR) primers, hybridization matrices, thermal cyclers, imagers, and software packages. The detection of the Factor V Leiden mutation aids in the diagnosis of patients with suspected thrombophilia.
B.7290	Factor deficiency test	2	A factor deficiency test is a device used to diagnose specific coagulation defects, to monitor certain types of therapy, to detect coagulation inhibitors, and to detect a carrier state (a person carrying both a recessive gene for a coagulation factor deficiency such as hemophilia and the corresponding normal gene).
B.7300	Fibrin monomer paracoagulation test	2	A fibrin monomer paracoagulation test is a device used to detect fibrin monomer in the diagnosis of disseminated intravascular coagulation (nonlocalized clotting within a blood vessel) or in the differential diagnosis between disseminated intravascular coagulation and primary fibrinolysis (dissolution of the fibrin in a blood clot).
B.7320	Fibrinogen/fibrin degradation products assay	2	A fibrinogen/fibrin degradation products assay is a device used to detect and measure fibrinogen degradation products and fibrin degradation products (protein fragments produced by the enzymatic action of plasmin on fibrinogen and fibrin) as an aid in detecting the presence and degree of intravascular coagulation and fibrinolysis (the dissolution of the fibrin in a blood clot) and in monitoring therapy for disseminated intravascular coagulation (nonlocalized clotting in the blood vessels).
B.7340	Fibrinogen determination system	2	A fibrinogen determination system is a device that consists of the instruments, reagents, standards, and controls used to determine the fibrinogen levels in disseminated intravascular coagulation (nonlocalized clotting within the blood vessels) and primary fibrinolysis (the dissolution of fibrin in a blood clot).
B.7360	Erythrocytic glucose-6-phosphate dehydrogenase assay	2	An erythrocytic glucose-6-phosphate dehydrogenase assay is a device used to measure the activity of the enzyme glucose-6-phosphate dehydrogenase or of glucose-6-phosphate dehydrogenase isoenzymes. The results of this assay are used in the diagnosis and treatment of nonspherocytic congenital hemolytic anemia or drug-induced hemolytic anemia associated with a glucose-6-phosphate dehydrogenase deficiency. This generic device includes assays based on fluorescence, electrophoresis, methemoglobin reduction, catalase inhibition, and ultraviolet kinetics.
B.7375	Glutathione reductase assay	2	A glutathione reductase assay is a device used to determine the activity of the enzyme glutathione reductase in serum, plasma, or erythrocytes by such techniques as fluorescence and photometry. The results of this assay are used in the diagnosis of liver disease, glutathione reductase deficiency, or riboflavin deficiency.
B.7400	Hemoglobin A2 assay	2	A hemoglobin A2assay is a device used to determine the hemoglobin A2content of human blood. The measurement of hemoglobin A2is used in the diagnosis of the thalassemias (hereditary hemolytic anemias characterized by decreased synthesis of one or more types of hemoglobin polypeptide chains).

B.7415	Abnormal hemoglobin assay	2	An abnormal hemoglobin assay is a device consisting of the reagents, apparatus, instrumentation, and controls necessary to isolate and identify abnormal genetically determined hemoglobin types.
B.7425	Carboxyhemoglobin assay	2	A carboxyhemoglobin assay is a device used to determine the carboxyhemoglobin (the compound formed when hemoglobin is exposed to carbon monoxide) content of human blood as an aid in the diagnosis of carbon monoxide poisoning. This measurement may be made using methods such as spectroscopy, colorimetry, spectrophotometry, and gasometry.
B.7440	Electrophoretic hemoglobin analysis system	2	An electrophoretic hemoglobin analysis system is a device that electrophoretically separates and identifies normal and abnormal hemoglobin types as an aid in the diagnosis of anemia or erythrocytosis (increased total red cell mass) due to a hemoglobin abnormality.
B.7455	Fetal hemoglobin assay	2	A fetal hemoglobin assay is a device that is used to determine the presence and distribution of fetal hemoglobin (hemoglobin F) in red cells or to measure the amount of fetal hemoglobin present. The assay may be used to detect fetal red cells in the maternal circulation or to detect the elevated levels of fetal hemoglobin exhibited in cases of hemoglobin abnormalities such as thalassemia (a hereditary hemolytic anemia characterized by a decreased synthesis of one or more types of hemoglobin polypeptide chains). The hemoglobin determination may be made by methods such as electrophoresis, alkali denaturation, column chromatography, or radial immunodiffusion.
B.7470	Glycosylated hemoglobin assay	2	A glycosylated hemoglobin assay is a device used to measure the glycosylated hemoglobins (A1a, A1b, and A1c) in a patient's blood by a column chromatographic procedure. Measurement of glycosylated hemoglobin is used to assess the level of control of a patient's diabetes and to determine the proper insulin dosage for a patient. Elevated levels of glycosylated hemoglobin indicate uncontrolled diabetes in a patient.
B.7490	Sulfhemoglobin assay	2	A sulfhemoglobin assay is a device consisting of the reagents, calibrators, controls, and instrumentation used to determine the sulfhemoglobin (a compound of sulfur and hemoglobin) content of human blood as an aid in the diagnosis of sulfhemoglobinemia (presence of sulfhemoglobin in the blood due to drug administration or exposure to a poison). This measurement may be made using methods such as spectroscopy, colorimetry, spectrophotometry, or gasometry.
B.7500	Whole blood hemoglobin assays	2	A whole blood hemoglobin assay is a device consisting or reagents, calibrators, controls, or photometric or spectrophotometric instrumentation used to measure the hemoglobin content of whole blood for the detection of anemia. This generic device category does not include automated hemoglobin systems.
B.7525	Heparin assay	2	A heparin assay is a device used to determine the level of the anticoagulant heparin in the patient's circulation. These assays are quantitative clotting time procedures using the effect of heparin on activated coagulation factor X (Stuart factor) or procedures based on the neutralization of heparin by protamine sulfate (a protein that neutralizes heparin).

B.7660	Leukocyte alkaline phosphatase test	1	A leukocyte alkaline phosphatase test is a device used to identify the enzyme leukocyte alkaline phosphatase in neutrophilic granulocytes (granular leukocytes stainable by neutral dyes). The cytochemical identification of alkaline phosphatase depends on the formation of blue granules in cells containing alkaline phosphatase. The results of this test are used to differentiate chronic granulocytic leukemia (a malignant disease characterized by excessive overgrowth of granulocytes in the bone marrow) and reactions that resemble true leukemia, such as those occuring in severe infections and polycythemia (increased total red cell mass).
B.7675	Leukocyte peroxidase test	1	A leukocyte peroxidase test is a device used to distinguish certain myeloid cells derived from the bone marrow, i.e., neutrophils, eosinophils, and monocytes, from lymphoid cells of the lymphatic system and erythroid cells of the red blood cell series on the basis of their peroxidase activity as evidenced by staining. The results of this test are used in the differential diagnosis of the leukemias.
B.7695	Platelet factor 4 radioimmunoassay	2	A platelet factor 4 radioimmunoassay is a device used to measure the level of platelet factor 4, a protein released during platelet activation by radioimmunoassay. This device measures platelet activiation, which may indicate a coagulation disorder, such as myocardial infarction or coronary artery disease.
B.7720	Prothrombin consumption test	2	A prothrombin consumption tests is a device that measures the patient's capacity to generate thromboplastin in the coagulation process. The test also is an indirect indicator of qualitative or quantitative platelet abnormalities. It is a screening test for thrombocytopenia (decreased number of blood platelets) and hemophilia A and B.
B.7735	Prothrombin-proconvertin test and thrombotest	2	The prothrombin-proconvertin test and thrombotest are devices used in the regulation of coumarin therapy (administration of a coumarin anticoagulant such as sodium warfarin in the treatment of venous thrombosis and pulmonary embolism) and as a diagnostic test in conjunction with, or in place of, the Quick prothrombin time test to detect coagulation disorders.
B.7750	Prothrombin time test	2	A prothrombin time test is a device used as a general screening procedure for the detection of possible clotting factor deficiencies in the extrinsic coagulation pathway, which involves the reaction between coagulation factors III and VII, and to monitor patients receiving coumarin therapy (the administration of one of the coumarin anticoagulants in the treatment of venous thrombosis or pulmonary embolism).
B.7825	Sickle cell test	2	A sickle cell test is a device used to determine the sickle cell hemoglobin content of human blood to detect sickle cell trait or sickle cell diseases.
B.7875	Thrombin time test	2	A thrombin time test is a device used to measure fibrinogen concentration and detect fibrin or fibrinogen split products for the evaluation of bleeding disorders.
B.7900	Thromboplastin generation test	1	A thromboplastin generation test is a device used to detect and identify coagulation factor deficiencies and coagulation inhibitors.

B.7925	Partial thromboplastin time tests	2	A partial thromboplastin time test is a device used for primary screening for coagulation abnormalities, for evaluation of the effect of therapy on procoagulant disorders, and as an assay for coagulation factor deficiencies of the intrinsic coagulation pathway.
B.8100	Bothrops atrox reagent	2	A Bothrops atrox reagent is a device made from snake venom and used to determine blood fibrinogen levels to aid in the evaluation of disseminated intravascular coagulation (nonlocalized clotting in the blood vessels) in patients receiving heparin therapy (the administration of the anticoagulant heparin in the treatment of thrombosis) or as an aid in the classification of dysfibrinogenemia (presence in the plasma of functionally defective fibrinogen).
B.8150	Calibrator for cell indices	2	A calibrator for cell indices is a device that approximates whole blood or certain blood cells and that is used to set an instrument intended to measure mean cell volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC), or other cell indices. It is a suspension of particles or cells whose size, shape, concentration, and other characteristics have been precisely and accurately determined.
B.8165	Calibrator for hemoglobin or hematocrit measurement	2	A calibrator for hemoglobin or hematocrit measurement is a device that approximates whole blood, red blood cells, or a hemoglobin derivative and that is used to set instruments intended to measure hemoglobin, the hematocrit, or both. It is a material whose characteristics have been precisely and accurately determined.
B.8175	Calibrator for platelet counting	2	A calibrator for platelet counting is a device that resembles platelets in plasma or whole blood and that is used to set a platelet counting instrument. It is a suspension of particles or cells whose size, shape concentration, and other characteristics have been precisely and accurately determined.
B.8185	Calibrator for red cell and white cell counting	2	A calibrator for red cell and white cell counting is a device that resembles red or white blood cells and that is used to set instruments intended to count red cells, white cells, or both. It is a suspension of particles or cells whose size, shape, concentration, and other characteristics have been precisely and accurately determined.
B.8200	Blood cell diluent	1	A blood cell diluent is a device used to dilute blood for further testing, such as blood cell counting.
B.8500	Lymphocyte separation medium	1	A lymphocyte separation medium is a device used to isolate lymphocytes from whole blood.
B.8540	Red cell lysing reagent	1	A red cell lysing reagent is a device used to lyse (destroy) red blood cells for hemoglobin determinations or aid in the counting of white blood cells.
B.8625	Hematology quality control mixture	2	A hematology quality control mixture is a device used to ascertain the accuracy and precision of manual, semiautomated, and automated determinations of cell parameters such as white cell count (WBC), red cell count (RBC), platelet count (PLT), hemoglobin, hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC).
B.8950	Russell viper venom reagent	1	Russell viper venom reagent is a device used to determine the cause of an increase in the prothrombin time.

B.9050	Blood bank supplies	1	Blood bank supplies are general purpose devices intended for in vitro use in blood banking. This generic type of device includes products such as blood bank pipettes, blood grouping slides, blood typing tubes, blood typing racks, cold packs for antisera reagents, and tube stripper.
B.9100	Empty container for the collection and processing of blood and blood components	2	An empty container for the collection and processing of blood and blood components is a device intended for medical purposes that is an empty plastic bag or plastic or glass bottle used to collect, store, or transfer blood and blood components for further processing.
B.9125	Vacuum-assisted blood collection system	1	A vacuum-assisted blood collection system is a device intended for medical purposes that uses a vacuum to draw blood for subsequent reinfusion.
B.9145	Processing system for frozen blood	2	A processing system for frozen blood is a device used to glycerolize red blood cells prior to freezing to minimize hemolysis (disruption of the red cell membrane accompanied by the release of hemoglobin) due to freezing and thawing of red blood cells and to deglycerolize and wash thawed cells for subsequent reinfusion.
B.9165	Blood establishment computer software	2	Blood establishment computer software (BECS) is a device used in the manufacture of blood and blood components to assist in the prevention of disease in humans by identifying ineligible donors, by preventing the release of unsuitable blood and blood components for transfusion or for further manufacturing into products for human treatment or diagnosis, by performing compatibility testing between donor and recipient, or by performing positive identification of patients and blood components at the point of transfusion to prevent transfusion reactions. This generic type of device may include a BECS accessory, a device intended for use with BECS to augment the performance of the BECS or to expand or modify its indications for use.
B.9175	Automated blood grouping and antibody test system	2	An automated blood grouping and antibody test system is a device used to group erythrocytes (red blood cells) and to detect antibodies to blood group antigens.
B.9195	Blood mixing devices and blood weighing devices	1	A blood mixing device is a device intended for medical purposes that is used to mix blood or blood components by agitation. A blood weighing device is a device intended for medical purposes that is used to weigh blood or blood components as they are collected.
B.9205	Blood and plasma warming device	2,3	(a)Nonelectromagnetic blood or plasma warming device --(1)Identification: A nonelectromagnetic blood and plasma warming device is a device that warms blood or plasma, by means other than electromagnetic radiation, prior to administration.(2)Classification: Class 2. (b)Electromagnetic blood and plasma warming device --(1)Identification. An electromagnetic blood and plasma warming device is a device that employs electromagnetic radiation (radiowaves or microwaves) to warm a bag or bottle of blood or plasma prior to administration. (2)Classification: Class 3.
B.9225	Cell-freezing apparatus and reagents for in vitro diagnostic use	1	Cell-freezing apparatus and reagents for in vitro diagnostic use are devices used to freeze human red blood cells for in vitro diagnostic use.

B.9245	Automated blood cell separator	2	An automated blood cell separator is a device that uses a centrifugal or filtration separation principle to automatically withdraw whole blood from a donor, separate the whole blood into blood components, collect one or more of the blood components, and return to the donor the remainder of the whole blood and blood components. The remainder of blood components is intended for transfusion or further manufacturing use. The device is operated by centrifugal or filtration separation principle. The bowl of the separator is reusable or for single use.
B.9275	Blood bank centrifuge for in vitro diagnostic use	1	A blood bank centrifuge for in vitro diagnostic use is a device used only to separate blood cells for further diagnostic testing.
B.9285	Automated cell-washing centrifuge for immuno-hematology	2	An automated cell-washing centrifuge for immuno-hematology is a device used to separate and prepare cells and sera for further in vitro diagnostic testing.
B.9300	Automated Coombs test systems	2	An automated Coombs test system is a device used to detect and identify antibodies in patient sera or antibodies bound to red cells. The Coombs test is used for the diagnosis of hemolytic disease of the newborn, and autoimmune hemolytic anemia. The test is also used in crossmatching and in investigating transfusion reactions and drug-induced red cell sensitization.
B.9320	Copper sulfate solution for specific gravity determinations	1	A copper sulfate solution for specific gravity determinations is a device used to determine whether the hemoglobin content of a potential donor's blood meets the required level (12.5 grams per 100 milliliters of blood for women and 13.5 grams per 100 milliliters of blood for men).
B.9400	Stabilized enzyme solution	2	A stabilized enzyme solution is a reagent intended for medical purposes that is used to enhance the reactivity of red blood cells with certain antibodies, including antibodies that are not detectable by other techniques. These enzyme solutions include papain, bromelin, ficin, and trypsin.
B.9550	Lectins and protectins	1	Lectins and protectins are proteins derived from plants and lower animals that cause cell agglutination in the presence of certain antigens. These substances are used to detect blood group antigens for in vitro diagnostic purposes.
B.9575	Environmental chamber for storage of platelet concentrate	1	An environmental chamber for storage of platelet concentrate is a device used to hold platelet-rich plasma within a preselected temperature range.
B.9600	Potentiating media for in vitro diagnostic use	1	Potentiating media for in vitro diagnostic use are media, such as bovine albumin, that are used to suspend red cells and to enhance cell reactions for antigen-antibody testing.
B.9650	Quality control kit for blood banking reagents	2	A quality control kit for blood banking reagents is a device that consists of sera, cells, buffers, and antibodies used to determine the specificity, potency, and reactivity of the cells and reagents used for blood banking.
B.9700	Blood storage refrigerator and blood storage freezer	1	A blood storage refrigerator and a blood storage freezer are devices intended for medical purposes that are used to preserve blood and blood products by storing them at cold or freezing temperatures.

B.9750	Heat-sealing device	1	A heat-sealing device is a device intended for medical purposes that uses heat to seal plastic bags containing blood or blood components.
B.9875	Transfer set	2	A transfer set is a device intended for medical purposes that consists of a piece of tubing with suitable adaptors used to transfer blood or plasma from one container to another.
B.9900	Cord blood processing system and storage container	2	A cord blood processing system and storage container is a device intended for use in the processing and the storage of cord blood. This device is a functionally closed processing system that includes containers, other soft goods, and a centrifugation system for cord blood concentration, and a final container for the cryopreservation and the storage of a cord blood product.
B.9999	Others(Hematology and Pathology Devices)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.
C.0001	Enterovirus 71 serological reagents	2	Enterovirus 71 serological reagents are devices that consist of antigens and antisera used to detect serum enterovirus antibodies in serological tests. Additionally, some of these reagents consist of enterovirus antisera conjugated with a fluorescent dye which used to detect enterovirus from clinical specimens or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of enterovirus infections and provides epidemiological information on diseases caused by these viruses. Enterovirus cause illnesses such as hand, foot and mouth diseases which in its serious form affect the central nervous system resulting in encephalitis, viral meningitis or/and paralysis.
C.0002	Dengue virus serological reagents	2	Dengue virus serological reagents are devices that consist of antigens and antisera for the detection of dengue antibodies in serological tests. This detection aids in diagnosis of diseases caused by dengue virus and provides epidemiological information on diseases caused by these viruses. These diseases are transmitted by mosquitos. The symptoms of these are similar to influenza including fever, fatigue, cough, and headache. The worst symptom is dengue hemorrhagic fever or dengue shock syndrome.
C.0003	Helicobacter spp. serological reagents	1	Helicobacter spp. serological reagents are devces consist of helicobacter antisera conjugated with a fluorescent dye which used to detect Helicobacter pylori from clinical specimens or from cultured isolates derived from clinical specimens. This identification aids in the diagnosis of Helicobacter pylori infections and provides epidemiological information on diseases caused by these viruses. Helicobacter pylori causes illnesses such as stomach ulcers, stomach inflammation (gastritis) leading to upper abdominal pain and bleeding.
C.0004	Human papillomavirus serological reagents	3	Human papillomavirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify Human papillomavirus antibodies in serum. The identification aids in the diagnosis of cervical cancer, identifies immune status of patients, and provides epidemiological information on diseases caused by these viruses.

C.0005	Plasmodium spp. serological reagents	2	Plasmodium spp. serological reagents are devices that consist of antigens and antisera used in serological tests to detect Plasmodium antibodies in serum. Additionally, some of these reagents consist of Plasmodium antisera conjugated with a fluorescent dye used to identify Plasmodium from clinical specimens. The identification aids in the diagnosis of Plasmodium infections and provides epidemiological information on diseases caused by these viruses. Plasmodium cause human malaria infections, which lead to fever, shiver, headache, muscle pain, arthralgia (joint pain). Untreated or unidentified diseases can cause severe cerebral malaria and fatal renal failure.
C.1620	Antimicrobial susceptibility test disc	2	An antimicrobial susceptibility test disc is a device that consists of antimicrobic-impregnated paper discs used to measure by a disc-agar diffusion technique or a disc-broth elution technique the in vitro susceptibility of most clinically important bacterial pathogens to antimicrobial agents. In the disc-agar diffusion technique, bacterial susceptibility is ascertained by directly measuring the magnitude of a zone of bacterial inhibition around the disc on an agar surface. The disc-broth elution technique is associated with an automated rapid susceptibility test system and employs a fluid medium in which susceptibility is ascertained by photometrically measuring changes in bacterial growth resulting when antimicrobial material is eluted from the disc into the fluid medium. Test results are used to determine the antimicrobial agent of choice in the treatment of bacterial diseases.
C.1640	Antimicrobial susceptibility test powder	2	An antimicrobial susceptibility test powder is a device that consists of an antimicrobial drug powder packaged in vials in specified amounts and intended for use in clinical laboratories for determining in vitro susceptibility of bacterial pathogens to these therapeutic agents. Test results are used to determine the antimicrobial agent of choice in the treatment of bacterial diseases.
C.1645	Fully automated short-term incubation cycle antimicrobial susceptibility system	2	A fully automated short-term incubation cycle antimicrobial susceptibility system is a device that incorporates concentrations of antimicrobial agents into a system for the purpose of determining in vitro susceptibility of bacterial pathogens isolated from clinical specimens. Test results obtained from short-term (less than 16 hours) incubation are used to determine the antimicrobial agent of choice to treat bacterial diseases.
C.1700	Culture medium for antimicrobial susceptibility tests	2	A culture medium for antimicrobial susceptibility tests is a device intended for medical purposes that consists of any medium capable of supporting the growth of many of the bacterial pathogens that are subject to antimicrobial susceptibility tests. The medium should be free of components known to be antagonistic to the common agents for which susceptibility tests are performed in the treatment of disease.
C.2160	Coagulase plasma	1	Coagulase plasma is a device that consists of freeze-dried animal or human plasma that is intended for medical purposes to perform coagulase tests primarily on staphylococcal bacteria. When reconstituted, the fluid plasma is clotted by the action of the enzyme coagulase which is produced by pathogenic staphylococci. Test results are used primarily as an aid in the diagnosis of disease caused by pathogenic bacteria belonging to the genusStaphylococcus and provide epidemiological information on disease caused by these microorganisms.

C.2170	Automated colony counter	1	An automated colony counter is a mechanical device intended for medical purposes to determine the number of bacterial colonies present on a bacteriological culture medium contained in a petri plate. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.
C.2190	Automated image sssessment system	2	An automated image assessment system for microbial colonies on solid culture media is a system that is intended to assess the presence or absence of microbial colonies on solid microbiological culture medium, and to interpret their number, and phenotypic and morphologic characteristics through analysis of two dimensional digital images as an aid in diagnosis of infectious disease.
C.2300	Multipurpose culture medium	1	A multipurpose culture medium is a device that consists primarily of liquid or solid biological materials intended for medical purposes for the cultivation and identification of several types of pathogenic microorganisms without the need of additional nutritional supplements. Test results aid in the diagnosis of disease and also provide epidemiological information on diseases caused by these microorganisms.
C.2320	Differential culture medium	1	A differential culture medium is a device that consists primarily of liquid biological materials intended for medical purposes to cultivate and identify different types of pathogenic microorganisms. The identification of these microorganisms is accomplished by the addition of a specific biochemical component(s) to the medium. Microorganisms are identified by a visible change (e.g., a color change) in a specific biochemical component(s) which indicates that specific metabolic reactions have occurred. Test results aid in the diagnosis of disease and also provide epidemiological information on diseases caused by these microorganisms.
C.2330	Enriched culture medium	1	An enriched culture medium is a device that consists primarily of liquid or solid biological materials intended for medical purposes to cultivate and identify fastidious microorganisms (those having complex nutritional requirements). The device consists of a relatively simple basal medium enriched by the addition of such nutritional components as blood, blood serum, vitamins, and extracts of plant or animal tissues. The device is used in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.
C.2350	Microbiological assay culture medium	1	A microbiological assay culture medium is a device that consists primarily of liquid or solid biological materials intended for medical purposes to cultivate selected test microorganisms in order to measure by microbiological procedures the concentration in a patient's serum of certain substances, such as amino acids, antimicrobial agents, and vitamins. The concentration of these substances is measured by their ability to promote or inhibit the growth of the test organism in the innoculated medium. Test results aid in the diagnosis of disease resulting from either deficient or excessive amounts of these substances in a patient's serum. Tests results may also be used to monitor the effects of the administration of certain antimicrobial drugs.

C.2360	Selective culture medium	1	A selective culture medium is a device that consists primarily of liquid or solid biological materials intended for medical purposes to cultivate and identify certain pathogenic microorganisms. The device contains one or more components that suppress the growth of certain microorganisms while either promoting or not affecting the growth of other microorganisms. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.
C.2390	Transport culture medium	1	A transport culture medium is a device that consists of a semisolid, usually non-nutrient, medium that maintains the viability of suspected pathogens contained in patient specimens while in transit from the specimen collection area to the laboratory. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.
C.2410	Culture medium for pathogenic Neisseria spp	2	A culture medium for pathogenicNeisseria spp. is a device that consists primarily of liquid or solid biological materials used to cultivate and identify pathogenicNeisseria spp. The identification aids in the diagnosis of disease caused by bacteria belonging to the genusNeisseria, such as epidemic cerebrospinal meningitis, other meningococcal disease, and gonorrhea, and also provides epidemiological information on these microorganisms.
C.2420	Oxidase screening test for gonorrhea	3	An oxidase screening test for gonorrhea is an in vitro device that consists of the articles intended to identify by chemical reaction, cytochrome oxidase, an oxidizing enzyme that is associated with certain bacteria includingNeisseria gonorrhoeae. A sample of a male's urethral discharge is obtained on a swab which is placed into a wetting agent containing an ingredient that will react with cytochrome oxidase. When cytochrome oxidase is present, the swab turns a dark purple color within 3 minutes. Because it is unlikely that cytochrome oxidase-positive organisms other thanNeisseria gonorrhoeae are present in the urethral discharge of males, the identification of cytochrome oxidase with this device indicates presumptive infection of the patient with the causative agent of gonorrhea.
C.2450	Supplement for culture media	1	A supplement for culture media is a device, such as a vitamin or sugar mixture, that is added to a solid or liquid basal culture medium to produce a desired formulation and that is intended for medical purposes to enhance the growth of fastidious microorganisms (those having complex nutritional requirements). This device aids in the diagnosis of diseases caused by pathogenic microorganisms.
C.2480	Quality control kit for culture media	1	A quality control kit for culture media is a device that consists of paper discs (or other suitable materials), each impregnated with a specified, freeze-dried, viable microorganism, intended for medical purposes to determine if a given culture medium is able to support the growth of that microorganism. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.
C.2500	Microtiter diluting and dispensing device	1	A microtiter diluting and dispensing device is a mechanical device intended for medical purposes to dispense or serially dilute very small quantities of biological or chemical reagents for use in various diagnostic procedures.

C.2560	Microbial growth monitor	1	A microbial growth monitor is a device intended for medical purposes that measures the concentration of bacteria suspended in a liquid medium by measuring changes in light scattering properties, optical density, electrical impedance, or by making direct bacterial counts. The device aids in the diagnosis of disease caused by pathogenic microorganisms.
C.2580	Gas-generating device	1	A gas-generating device is a device intended for medical purposes that produces predetermined amounts of selected gases to be used in a closed chamber in order to establish suitable atmospheric conditions for cultivation of microorganisms with special atmospheric requirements. The device aids in the diagnosis of disease.
C.2600	Wood's fluorescent lamp	1	A Wood's fluorescent lamp is a device intended for medical purposes to detect fluorescent materials (e.g., fluorescein pigment produced by certain microorganisms) as an aid in the identification of these microorganisms. The device aids in the diagnosis of disease.
C.2660	Microorganism differentiation and identification device	1	A microorganism differentiation and identification device is a device intended for medical purposes that consists of one or more components, such as differential culture media, biochemical reagents, and paper discs or paper strips impregnated with test reagents, that are usually contained in individual compartments and used to differentiate and identify selected microorganisms. The device aids in the diagnosis of disease.
C.2850	Automated zone reader	1	An automated zone reader is a mechanical device intended for medical purposes to measure zone diameters of microbial growth inhibition (or exhibition), such as those observed on the surface of certain culture media used in disc-agar diffusion antimicrobial susceptibility tests. The device aids in decisionmaking respecting the treatment of disease.
C.2900	Microbiological specimen collection and transport device	1	A microbiological specimen collection and transport device is a specimen collecting chamber intended for medical purposes to preserve the viability or integrity of microorganisms in specimens during storage of specimens after their collection and during their transport from the collecting area to the laboratory. The device may be labeled or otherwise represented as sterile. The device aids in the diagnosis of disease caused by pathogenic microorganisms.
C.3010	Acinetobacter calcoaceticus serological reagents	1	Acinetobacter calcoaceticus serological reagents are devices that consist ofAcinetobacter calcoaceticus antigens and antisera used to identify this bacterium from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by the bacteriumAcinetobacter calcoaceticus and provides epidemiological information on disease caused by this microorganism. This organism becomes pathogenic in patients with burns or with immunologic deficiency, and infection can result in sepsis (blood poisoning).

C.3020	Adenovirus serological reagents	1	Adenovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to adenovirus in serum. Additionally, some of these reagents consist of adenovirus antisera conjugated with a fluorescent dye and are used to identify adenoviruses directly from clinical specimens. The identification aids in the diagnosis of disease caused by adenoviruses and provides epidemiological information on these diseases. Adenovirus infections may cause pharyngitis (inflammation of the throat), acute respiratory diseases, and certain external diseases of the eye (e.g., conjunctivitis).
C.3035	Arizona spp.serological reagents	1	Arizona spp. serological reagents are devices that consist of antisera and antigens used to identifyArizona spp. in cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genusArizona and provides epidemiological information on diseases caused by these microorganisms.Arizona spp. can cause gastroenteritis (food poisoning) and sepsis (blood poisoning).
C.3040	Aspergillus spp. serological reagents	1	Aspergillus spp. serological reagents are devices that consist of antigens and antisera used in various serological tests to identify antibodies toAspergillus spp. in serum. The identification aids in the diagnosis of aspergillosis caused by fungi belonging to the genusAspergillus. Aspergillosis is a disease marked by inflammatory granulomatous (tumor-like) lessions in the skin, ear, eyeball cavity, nasal sinuses, lungs, and occasionally the bones.
C.3050	Beta-glucan serological assays.	2	Beta-glucan serological assays are devices that consist of antigens or proteases used in serological assays. The device is intended for use for the presumptive diagnosis of fungal infection. The assay is indicated for use in patients with symptoms of, or medical conditions predisposing the patient to invasive fungal infection. The device can be used as an aid in the diagnosis of deep seated mycoses and fungemias.
C.3060	Blastomyces dermatitidis serological reagents	1	Blastomyces dermatitidis serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies toBlastomyces dermatitidis in serum. The identification aids in the diagnosis of blastomycosis caused by the fungusBlastomyces dermatitidis. Blastomycosis is a chronic granulomatous (tumor-like) disease, which may be limited to the skin or lung or may be widely disseminated in the body resulting in lesions of the bones, liver, spleen, and kidneys.
C.3065	Bordetella spp. serological reagents	1	Bordetella spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, used in serological tests to identifyBordetella spp. from cultured isolates or directly from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genusBordetella and provides epidemiological information on these diseases.Bordetella spp. cause whooping cough (Bordetella pertussis) and other similiarly contagious and acute respiratory infections characterized by pneumonitis (inflammation of the lungs).

C.3085	Brucella spp. serological reagents	1	Brucella spp. serological reagents are devices that consist of antigens and antisera used for serological identification ofBrucella spp. from cultured isolates derived from clinical specimens or to identify antibodies toBrucella spp. in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identifyBrucella spp. directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of brucellosis (e.g., undulant fever, Malta fever) caused by bacteria belonging to the genusBrucella and provides epidemiological information on diseases caused by these microorganisms.
C.3110	Campylobacter fetus serological reagents	1	Campylobacter fetus serological reagents are devices that consist of antisera conjugated with a fluorescent dye used to identifyCampylobacter fetus from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by this bacterium and provides epidemiological information on these diseases.Campylobacter fetus is a frequent cause of abortion in sheep and cattle and is sometimes responsible for endocarditis (inflammation of certain membranes of the heart) and enteritis (inflammation of the intestines) in humans.
C.3120	Chlamydia serological reagents	1	Chlamydia serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to chlamydia in serum. Additionally, some of these reagents consist of chlamydia antisera conjugated with a fluorescent dye used to identify chlamydia directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genusChlamydia and provides epidemiological information on these diseases. Chlamydia are the causative agents of psittacosis (a form of pneumonia), lymphogranuloma venereum (a venereal disease), and trachoma (a chronic disease of the eye and eyelid).
C.3125	Citrobacter spp.serological reagents	1	Citrobacter spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identifyCitrobacter spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genusCitrobacter and provides epidemiological information on diseases caused by these microorganisms.Citrobacter spp. have occasionally been associated with urinary tract infections.
C.3130	Clostridium difficile toxin gene amplification assay	2	A Clostridium difficile toxin gene amplification assay is a device that consists of reagents for the amplification and detection of target sequences in Clostridium difficile toxin genes in fecal specimens from patients suspected of having Clostridium difficile infection (CDI). The detection of clostridial toxin genes, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of CDI caused by Clostridium difficile.

C.3135	Coccidioides immitis serological reagents	1	Coccidioides immitis serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies toCoccidioides immitis in serum. The identification aids in the diagnosis of coccidioidomycosis caused by a fungus belonging to the genusCoccidioides and provides epidemiological information on diseases caused by this microorganism. An infection withCoccidioides immitis produces symptoms varying in severity from those accompanying the common cold to those of influenza.
C.3140	Corynebacterium spp.serological reagents	1	Corynebacterium spp. serological reagents are devices that consist of antisera conjugated with a fluorescent dye used to identifyCorynebacterium spp. from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genusCorynebacterium and provides epidemiological information on diseases caused by these microorganisms. The principal human pathogen of this genus,Corynebacterium diphtheriae, causes diphtheria. However, many other types of corynebacteria form part of the normal flora of the human respiratory tract, other mucus membranes, and skin, and are either nonpathogenic or have an uncertain role.
C.3145	Coxsackievirus serological reagents	1	Coxsackievirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to coxsackievirus in serum. Additionally, some of these reagents consist of coxsackievirus antisera conjugated with a fluorescent dye that are used to identify coxsackievirus from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of coxsackievirus infections and provides epidemiological information on diseases caused by these viruses. Coxsackieviruses produce a variety of infections, including common colds, meningitis (inflammation of brain and spinal cord membranes), herpangina (brief fever accompanied by ulcerated lesions of the throat), and myopericarditis (inflammation of heart tissue).
C.3165	Cryptococcus neoformans serological reagents	1	Cryptococcus neoformans serological reagents are devices that consist of antigens used in serological tests to identify antibodies toCryptococcus neoformans in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) and are used to identifyCryptococcus neoformans directly from clinical specimens or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of cryptococcosis and provides epidemiological information on this type of disease. Cryptococcosis infections are found most often as chronic meningitis (inflammation of brain membranes) and, if not treated, are usually fatal.

C.3175	Cytomegalovirus serological reagents	2	Cytomegalovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to cytomegalovirus in serum. The identification aids in the diagnosis of diseases caused by cytomegaloviruses (principally cytomegalic inclusion disease) and provides epidemiological information on these diseases. Cytomegalic inclusion disease is a generalized infection of infants and is caused by intrauterine or early postnatal infection with the virus. The disease may cause severe congenital abnormalities, such as microcephaly (abnormal smallness of the head), motor disability, and mental retardation. Cytomegalovirus infection has also been associated with acquired hemolytic anemia, acute and chronic hepatitis, and an infectious mononucleosis-like syndrome.
C.3200	Echinococcus spp. serological reagents	1	Echinococcus spp. serological reagents are devices that consist ofEchinococcus spp. antigens and antisera used in serological tests to identify antibodies toEchinococcus spp. in serum. The identification aids in the diagnosis of echinococcosis, caused by parasitic tapeworms belonging to the genusEchinococcus and provides epidemiological information on this disease. Echinococcosis is characterized by the development of cysts in the liver, lung, kidneys, and other organs formed by the larva of the infecting organisms.
C.3205	Echovirus serological reagents	1	Echovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to echovirus in serum. Additionally, some of these reagents consist of echovirus antisera conjugated with a fluorescent dye used to identify echoviruses from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of echovirus infections and provides epidemiological information on diseases caused by these viruses. Echoviruses cause illnesses such as meningitis (inflammation of the brain and spinal cord membranes), febrile illnesses (accompanied by fever) with or without rash, and the common cold.
C.3210	Endotoxin assay.	2	An endotoxin assay is a device that uses serological techniques in whole blood. The device is intended for use in conjunction with other laboratory findings and clinical assessment of the patient to aid in the risk assessment of critically ill patients for progression to severe sepsis.
C.3215	Device to detect and measure non-microbial analyte(s) for patients with suspected sepsis	2	A device to detect and measure non-microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis is identified as an in vitro device intended for the detection and qualitative and/or quantitative measurement of one or more non-microbial analytes in human clinical specimens to aid in the assessment of patients with suspected sepsis when used in conjunction with clinical signs and symptoms and other clinical and laboratory findings.

C.3220	Entamoeba histolytica serological reagents	1	Entamoeba histolytica serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies toEntamoeba histolytica in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identifyEntamoeba histolytica directly from clinical specimens. The identification aids in the diagnosis of amebiasis caused by the microscopic protozoan parasiteEntamoeba histolytica and provides epidemiological information on diseases caused by this parasite. The parasite may invade the skin, liver, intestines, lungs, and diaphragm, causing disease conditions such as indolent ulcers, an amebic hepatitis, amebic dysentery, and pulmonary lesions.
C.3225	Enterovirus nucleic acid assay	2	An enterovirus nucleic acid assay is a device that consists of primers, probes, enzymes, and controls for the amplification and detection of enterovirus ribonucleic acid (RNA) in cerebrospinal fluid (CSF) from individuals who have signs and symptoms consistent with meningitis or meningoencephalitis. The detection of enterovirus RNA, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of viral meningitis caused by enterovirus.
C.3235	Epstein-Barr virus serological reagents	1,2	Epstein-Barr virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Epstein-Barr virus in serum. The identification aids in the diagnosis of Epstein-Barr virus infections and provides epidemiological information on diseases caused by these viruses. Epstein-Barr viruses are thought to cause infectious mononucleosis and have been associated with Burkitt's lymphoma (a tumor of the jaw in African children and young adults) and postnasal carcinoma (cancer).Classification: (1)Class1 devices for diagnosis of infectious mononucleosis (2)Class 2 devices for diagnosis, prognosis and treatment of Burkitt's lymphoma, postnasal carcinoma, and other cancer.
C.3240	Equine encephalomyelitis virus serological reagents	1	Equine encephalomyelitis virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antobodies to equine encephalomyelitis virus in serum. The identification aids in the diagnosis of diseases caused by equine encephalomyelitis viruses and provides epidemiological information on these viruses. Equine encephalomyelitis viruses are transmitted to humans by the bite of insects, such as mosquitos and ticks, and may cause encephalitis (inflammation of the brain), rash, acute arthritis, or hepatitis.
C.3250	Erysipelothrix rhusiopathiae serological reagents	1	Erysipelothrix rhusiopathiae serological reagents are devices that consist of antigens and antisera used in serological tests to identifyErysipelothrix rhusiopathiae from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genusErysipelothrix. This organism is responsible for a variety of inflammations of the skin following skin abrasions from contact with fish, shellfish, or poultry.

C.3255	Escherichia coli serological reagents	1	Escherichia coli serological reagents are devices that consist of antigens and antisera used in serological tests to identifyEscherichia coli from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist ofEscherichia coli antisera conjugated with a fluorescent dye used to identifyEscherichia coli directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by this bacterium belonging to the genusEscherichia, and provides epidemiological information on diseases caused by this microorganism. AlthoughEscherichia coli constitutes the greater part of the microorganisms found in the intestinal tract in humans and is usually nonpathogenic, those strains which are pathogenic may cause urinary tract infections or epidemic diarrheal disease, especially in children.
C.3270	Flavobacterium spp. serological reagents	1	Flavobacterium spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identifyFlavobacteriuim spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genusFlavobacterium and provides epidemiological information on diseases caused by these microorganisms. Most members of this genus are found in soil and water and, under certain conditions, may become pathogenic to humans.Flavobacterium meningosepticum is highly virulent for the newborn, in whom it may cause epidemics of septicemia (blood poisoning) and meningitis (inflammation of the membranes of the brain) and is usually attributable to contaminated hospital equipment.
C.3280	Francisella tularensis serological reagents	1	Francisella tularensis serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies toFrancisella tularensis in serum or to identifyFrancisella tularensis in cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identifyFrancisella tularensis directly from clinical specimens. The identification aids in the diagnosis of tularemia caused byFrancisella tularensis and provides epidemiological information on this disease. Tularemia is a desease principally of rodents, but may be transmitted to humans through handling of infected animals, animal products, or by the bites of fleas and ticks. The disease takes on several forms depending upon the site of infection, such as skin lesions, lymph node enlargements, or pulmonary infection.
C.3290	Gonococcal antibody test GAT	3	A gonococcal antibody test (GAT) is an in vitro device that consists of the reagents intended to identify by immunochemical techniques, such as latex agglutination, indirect fluorescent antibody, or radioimmunoassay, antibodies toNeisseria gonorrhoeae in sera of asymptomatic females at low risk of infection. Identification of antibodies with this device may indicate past or present infection of the patient withNeisseria gonorrhoeae.

C.3300	Haemophilus spp. serological reagents	1	Haemophilus spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, that are used in serological tests to identifyHaemophilus spp. directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genusHaemophilus and provides epidemiological information on diseases cause by these microorganisms. Diseases most often caused by Haemophilus spp. include pneumonia, pharyngitis, sinusitis, vaginitis, chancroid venereal disease, and a contagious form of conjunctivitis (inflammation of eyelid membranes).
C.3305	Herpes simplex virus serological reagents	2,3	Herpes simplex virus serological assays are devices that consist of antigens and antisera used in various serological tests to identify antibodies to herpes simplex virus in serum. Additionally, some of the assays consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent assays) used to identify herpes simplex virus directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by herpes simplex viruses and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe form of encephalitis (inflammation of the brain). Neonatal herpes virus infections range from a mild infection to a severe generalized disease with a fatal outcome.Classification:(1)Class 2 devices for HSV1 and/or HSV2 identification.； (2)Class 3 deivces for other types of HSV identification.
C.3309	Herpes virus nucleic acid-based cutaneous and mucocutaneous lesion panel	2	A herpes virus nucleic acid-based cutaneous and mucocutaneous lesion panel is a qualitative in vitro diagnostic device intended for the simultaneous detection and differentiation of different herpes viruses in cutaneous and mucocutaneous lesion samples from symptomatic patients suspected of Herpetic infections. Negative results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions. The assay is not intended for use in cerebrospinal fluid samples.
C.3320	Histoplasma capsulatum serological ragents	1	Histoplasma capsulatum serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies toHistoplasma capsulatum in serum. Additionally, some of these reagents consist ofHistoplasma capsulatum antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identifyHistoplasma capsulatum from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of histoplasmosis caused by this fungus belonging to the genusHistoplasma and provides epidemiological information on the diseases caused by this fungus. Histoplasmosis usually is a mild and often asymptomatic respiratory infection, but in a small number of infected individuals the lesions may spread to practically all tissues and organs.

C.3328	Influenza virus antigen detection test system	2	An influenza virus antigen detection test system is a device for qualitative (rapid screening) detection of influenza virus infection directly from clinical specimens of patients with respiratory symptoms and signs. The test aids in the diagnosis of influenza infection and provides epidemiological information on influenza. Due to the propensity of the virus to mutate, new strains emerge over time which may potentially affect the performance of these devices. Because influenza is highly contagious and may lead to an acute respiratory tract infection causing severe illness and even death, the accuracy of these devices has serious public health implications.
C.3330	Influenza virus serological reagents	1	Influenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to influenza in serum. The identification aids in the diagnosis of influenza (flu) and provides epidemiological information on influenza. Influenza is an acute respiratory tract disease, which is often epidemic.This classification does not include devices for qualitative (rapid screening) detection of influenza virus infection directly from clinical specimens of patients with respiratory symptoms and signs.
C.3332	Reagents for detection of specific novel influenza A viruses.	2	Reagents for detection of specific novel influenza A viruses are devices that are intended for use in a nucleic acid amplification test to directly detect specific virus RNA in human respiratory specimens or viral cultures. Detection of specific virus RNA aids in the diagnosis of influenza caused by specific novel influenza A viruses in patients with clinical risk of infection with these viruses, and also aids in the presumptive laboratory identification of specific novel influenza A viruses to provide epidemiological information on influenza. These reagents include primers, probes, and specific influenza A virus controls.
C.3336	John Cunningham Virus serological reagents	2	John Cunningham Virus serological reagents are devices that consist of antigens and antisera used in serological assays to identify antibodies to John Cunningham Virus in serum and plasma. The identification aids in the risk stratification for the development of progressive multifocal leukoencephalopathy in multiple sclerosis and Crohn's disease patients undergoing natalizumab therapy. These devices are for adjunctive use, in the context of other clinical risk factors for the development of progressive multifocal leukoencephalopathy.
C.3340	Klebsiella spp. serological reagents	1	Klebsiella spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), that are used in serological tests to identifyKlebsiella spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genusKlebsiella and provides epidemiological information on these diseases. These organisms can cause serious urinary tract and pulmonary infections, particularly in hospitalized patients.

C.3350	Leptospira spp. serological reagents	1	Leptospira spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies toLeptospira spp. in serum or identifyLeptospira spp. from cultured isolates derived from clinical specimens. Additionally, some of these antisera are conjugated with a fluorescent dye (immunofluorescent reagents) and used to identifyLeptospira spp. directly from clinical specimens. The identification aids in the diagnosis of leptospirosis caused by bacteria belonging to the genusLeptospira and provides epidemiological information on this disease.Leptospira infections range from mild fever-producing illnesses to severe liver and kidney involvement producing hemorrhage and dysfunction of these organs.
C.3355	Listeria spp. serological reagents	1	Listeria spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identifyListeria spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist ofListeria spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identifyListeria spp. directly from clinical specimens. The identification aids in the diagnosis of listeriosis, a disease caused by bacteria belonging to the genusListeria, and provides epidemiological information on diseases caused by these microorganisms.Listeria monocytogenes, the most common human pathogen of this genus, causes meningitis (inflammation of the brain membranes) and meningoencephalitis (inflammation of the brain and brain membranes) and is often fatal if untreated. A second form of human listeriosis is an intrauterine infection in pregnant women that results in a high mortality rate for infants before or after birth.
C.3360	Lymphocytic chorimeningitis virus serological reagents	1	Lymphocytic choriomeningitis virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to lymphocytic choriomeningitis virus in serum. The identification aids in the diagnosis of lymphocytic choriomeningitis virus infections and provides epidemiological information on diseases caused by these viruses. Lymphocytic choriomeningitis viruses usually cause a mild cerebral meningitis (inflammation of membranes that envelop the brain) and occasionally a mild pneumonia, but in rare instances may produce severe and even fatal illnesses due to complications from cerebral meningitis and pneumonia.
C.3365	Multiplex nucleic acid assay for identification of microorganisms and resistance markers from positive blood cultures	2	A multiplex nucleic acid assay for identification of microorganisms and resistance markers from positive blood cultures is a qualitative in vitro device intended to simultaneously detect and identify microorganism nucleic acids from blood cultures that test positive by Gram stain or other microbiological stains. The device detects specific nucleic acid sequences for microorganism identification as well as for antimicrobial resistance. This device aids in the diagnosis of bloodstream infections when used in conjunction with other clinical and laboratory findings. However, the device does not replace traditional methods for culture and susceptibility testing.

C.3370	Mycobacterium tuberculosis immunofluorescent reagents	1	Mycobacterium tuberculosis immunofluorescent reagents are devices that consist of antisera conjugated with a fluorescent dye used to identifyMycobacterium tuberculosis directly from clinical specimens. The identification aids in the diagnosis of tuberculosis and provides epidemiological information on this disease.Mycobacterium tuberculosis is the common causative organism in human tuberculosis, a chronic infectious disease characterized by formation of tubercles (small rounded nodules) and tissue necrosis (destruction), usually occurring in the lung.
C.3372	Nucleic acid-based in vitro diagnostic devices for the detection of Mycobacterium tuberculosis complex in respiratory specimens	2	Nucleic acid-based in vitro diagnostic devices for the detection of Mycobacterium tuberculosis complex in respiratory specimens are qualitative nucleic acid-based in vitro diagnostic devices intended to detect Mycobacterium tuberculosis complex nucleic acids extracted from human respiratory specimens. These devices are non-multiplexed and intended to be used as an aid in the diagnosis of pulmonary tuberculosis when used in conjunction with clinical and other laboratory findings. These devices do not include devices intended to detect the presence of organism mutations associated with drug resistance. Respiratory specimens may include sputum (induced or expectorated), bronchial specimens (e.g., bronchoalveolar lavage or bronchial aspirate), or tracheal aspirates.
C.3373	Nucleic acid-based in vitro diagnostic devices for the detection of Mycobacterium tuberculosis complex (MTB-complex) and the genetic mutations associated with MTB-complex antibiotic resistance in respiratory specimens	2	Nucleic acid-based in vitro diagnostic devices for the detection of Mycobacterium tuberculosis complex (MTB-complex) and the genetic mutations associated with MTB-complex antibiotic resistance in respiratory specimens are qualitative nucleic acid-based devices that detect the presence of MTB-complex-associated nucleic acid sequences in respiratory samples. These devices are intended to aid in the diagnosis of pulmonary tuberculosis and the selection of an initial treatment regimen when used in conjunction with clinical findings and other laboratory results. These devices do not provide confirmation of antibiotic susceptibility since other mechanisms of resistance may exist that may be associated with a lack of clinical response to treatment other than those detected by the device.
C.3375	Mycoplasma spp. serological reagents	1	Mycoplasma spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies toMycoplasma spp. in serum. Additionally, some of these reagents consist ofMycoplasma spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identifyMycoplasma spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genusMycoplasma and provides epidemiological information on diseases caused by these microorganisms. Mycoplasma spp. are associated with inflammatory conditions of the urinary and respiratory tracts, the genitals, and the mouth. The effects in humans of infection withMycoplasma pneumoniae range from inapparent infection to mild or severe upper respiratory disease, ear infection, and bronchial pneumonia.

C.3380	Mumps virus serological reagents	1	Mumps virus serological reagents consist of antigens and antisera used in serological tests to identify antibodies to mumps virus in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used in serological tests to identify mumps viruses from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of mumps and provides epidemiological information on mumps. Mumps is an acute contagious disease, particularly in children, characterized by an enlargement of one or both of the parotid glands (glands situated near the ear), although other organs may also be involved.
C.3390	Neisseria spp. Direct serological test reagents	2	Neisseria spp. direct serological test reagents are devices that consist of antigens and antisera used in serological tests to identifyNeisseria spp. from cultured isolates. Additionally, some of these reagents consist ofNeisseria spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) which may be used to detect the presence ofNeisseria spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genusNeisseria, such as epidemic cerebrospinal meningitis, meningococcal disease, and gonorrhea, and also provides epidemiological information on diseases caused by these microorganisms. The device does not include products for the detection of gonorrhea in humans by indirect methods, such as detection of antibodies or of oxidase produced by gonococcal organisms.
C.3395	Norovirus serological reagents	2	Norovirus serological reagents are devices that consist of antigens and antisera used in serological tests to detect the presence of norovirus antigens in fecal samples. These devices aid in the diagnosis of norovirus infection in the setting of an individual patient with symptoms of acute gastroenteritis when the individual patient is epidemiologically linked to other patients with symptoms of acute gastroenteritis and/or aid in the identification of norovirus as the etiology of an outbreak of acute gastroenteritis in the setting of epidemiologically linked patients with symptoms of acute gastroenteritis.Classification. Class II
C.3400	Parainfluenza virus serological reagents	1	Parainfluenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to parainfluenza virus in serum. The identification aids in the diagnosis of parainfluenza virus infections and provides epidemiological information on diseases caused by these viruses. Parainfluenza viruses cause a variety of respiratory illnesses ranging from the common cold to pneumonia.

C.3402	Plasmodium species antigen detection assays	2	APlasmodium species antigen detection assay is a device that employs antibodies for the detection of specific malaria parasite antigens, including histidine-rich protein-2 (HRP2) specific antigens, and pan malarial antigens in human whole blood. These devices are used for testing specimens from individuals who have signs and symptoms consistent with malaria infection. The detection of these antigens aids in the clinical laboratory diagnosis of malaria caused by the four malaria species capable of infecting humans:Plasmodium falciparum ,Plasmodium vivax ,Plasmodium ovale , andPlasmodium malariae , and aids in the differential diagnosis ofPlasmodium falciparum infections from other less virulentPlasmodium species. The device is intended for use in conjunction with other clinical laboratory findings.
C.3405	Poliovirus serological reagents	1	Poliovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to poliovirus in serum. Additionally, some of these reagents consist of poliovirus antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify polioviruses from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of poliomyelitis (polio) and provides epidemiological information on this disease. Poliomyelitis is an acute infectious disease which in its serious form affects the central nervous system resulting in atrophy (wasting away) of groups of muscles, ending in contraction and permanent deformity.
C.3410	Proteus spp. (Weil-Felix) serological reagents	1	Proteus spp. (Weil-Felix) serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), derived from the bacteriumProteus vulgaris used in agglutination tests (a specific type of antigen-antibody reaction) for the detection of antibodies to rickettsia (virus-like bacteria) in serum. Test results aid in the diagnosis of diseases caused by bacteria belonging to the genusRickettsiae and provide epidemiological information on these diseases. Rickettsia are generally transmitted by arthropods (e.g., ticks and mosquitoes) and produce infections in humans characterized by rash and fever (e.g., typhus fever, spotted fever, Q fever, and trench fever).
C.3415	Pseudomonas spp. serological reagents	1	Pseudomonas spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), used to identifyPseudomonas spp. from clinical specimens or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genusPseudomonas. Pseudomonas aeruginosa is a major cause of hospital-acquired infections, and has been associated with urinary tract infections, eye infections, burn and wound infections, blood poisoning, abscesses, and meningitis (inflammation of brain membranes).Pseudomonas pseudomallei causes melioidosis, a chronic pneumonia.

C.3460	Rabiesvirus immunofluorescent reagents	2	Rabiesvirus immunofluorescent reagents are devices that consist of rabiesvirus antisera conjugated with a fluorescent dye used to identify rabiesvirus in specimens taken from suspected rabid animals. The identification aids in the diagnosis of rabies in patients exposed by animal bites and provides epidemiological information on rabies. Rabies is an acute infectious disease of the central nervous system which, if undiagnosed, may be fatal. The disease is commonly transmitted to humans by a bite from a rabid animal.
C.3470	Reovirus serological reagents	1	Reovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to reovirus in serum. The identification aids in the diagnosis of reovirus infections and provides epidemiological information on diseases caused by these viruses. Reoviruses are thought to cause only mild respiratory and gastrointestinal illnesses.
C.3480	Respiratory syncytial virus serological reagents	1	Respiratory syncytial virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to respiratory syncytial virus in serum. Additionally, some of these reagents consist of respiratory syncytial virus antisera conjugated with a fluorescent dye (immunofluorescent reagents) and used to identify respiratory syncytial viruses from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of respiratory syncytial virus infections and provides epidemiological information on diseases caused by these viruses. Respiratory syncytial viruses cause a number of respiratory tract infections, including the common cold, pharyngitis, and infantile bronchopneumonia.
C.3490	Rhinovirus serological reagents	1	Rhinovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rhinovirus in serum. The identification aids in the diagnosis of rhinovirus infections and provides epidemiological information on diseases caused by these viruses. Rhinoviruses cause common colds.
C.3500	Rickettsia serological reagents	1	Rickettsia serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rickettsia in serum. Additionally, some of these reagents consist of rickettsial antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify rickettsia directly from clinical specimens. The identification aids in the diagnosis of diseases caused by virus-like bacteria belonging to the genusRickettsiae and provides epidemiological information on these diseases. Rickettsia are generally transmitted by arthropods (e.g., ticks and mosquitoes) and produce infections in humans characterized by rash and fever (e.g., typhus fever, spotted fever, Q fever, and trench fever).
C.3510	Rubella virus serological reagents	2	Rubella virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rubella virus in serum. The identification aids in the diagnosis of rubella (German measles) or confirmation of a person's immune status from past infections or immunizations and provides epidemiological information on German measles. Newborns infected in the uterus with rubella virus may be born with multiple congenital defects (rubella syndrome).

C.3520	Rubeola (measles) virus serological reagents	1	Rubeola (measles) virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rubeola virus in serum. The identification aids in the diagnosis of measles and provides epidemiological information on the disease. Measles is an acute, highly infectious disease of the respiratory and reticuloendothelial tissues, particularly in children, characterized by a confluent and blotchy rash.
C.3550	Salmonella spp. serological reagents	1	Salmonella spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identifySalmonella spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identifySalmonella spp. directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of salmonellosis caused by bacteria belonging to the genusSalmonella and provides epidemiological information on this disease. Salmonellosis is characterized by high grade fever ("enteric fever"), severe diarrhea, and cramps.
C.3600	Schistosoma spp. serological reagents	1	Schistosoma spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies toSchistosoma spp. in serum. The identification aids in the diagnosis of schistosomiasis caused by parasitic flatworms of the genusSchistosoma. Schistosomiasis is characterized by a variety of acute and chronic infections. Acute infection is marked by fever, allergic symptoms, and diarrhea. Chronic effects are usually severe and are caused by fibrous degeneration of tissue around deposited eggs of the parasite in the liver, lungs, and central nervous system. Schistosomes can also cause schistosome dermatitis (e.g., swimmer's itch), a skin disease marked by intense itching.
C.3630	Serratia spp. serological reagents	1	Serratia spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identifySerratia spp. from cultured isolates. The identification aids in the diagnosis of disease caused by bacteria belonging to the genusSerratia and provides epidemiological information on these diseases.Serratia spp. are occasionally associated with gastroenteritis (food poisoning) and wound infections.
C.3660	Shigella spp.serological reagents	1	Shigella spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), used in serological tests to identifyShigella spp. from cultured isolates. The identification aids in the diagnosis of shigellosis caused by bacteria belonging to the genusShigella and provides epidemiological information on this disease. Shigellosis is characterized by abdominal pain, cramps, diarrhea, and fever.
C.3680	Sporothrix schenckii serological reagents	1	Sporothrix schenckii serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies toSporothrix schenckii in serum. The identification aids in the diagnosis of sporothrichosis caused by a fungus belonging to the genusSporothrix and provides epidemiological information on this disease. Sporothrichosis is a chronic tumorlike infection primarily of the skin.

C.3700	Staphylococcus aureus serological reagents	1	Staphylococcus aureus serological reagents are devices that consist of antigens and antisera used in serological tests to identify enterotoxin (toxin affecting the intestine) producing staphylococci from cultured isolates. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genusStaphylococcus and provides epidemiological information on these diseases. Certain strains ofStaphylococcus aureus produce an enterotoxin while growing in meat, dairy, or bakery products. After ingestion, this enterotoxin is absorbed in the gut and causes destruction of the intestinal lining (gastroenteritis).
C.3720	Streptococcus spp. exoenzyme reagents	1	Streptococcus spp. exoenzyme reagents are devices used to identify antibodies toStreptococcus spp. exoenzyme in serum. The identification aids in the diagnosis of disease caused by bacteria belonging to the genusStreptococcus and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, rheumatic fever, and kidney disease.
C.3740	Streptococcus spp. serological reagents	1	Streptococcus spp. serological reagents are devices that consist of antigens and antisera (excluding streptococcal exoenzyme reagents made from enzymes secreted by streptococci) used in serological tests to identifyStreptococcus spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genusStreptococcus and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, rheumatic fever, and kidney disease.
C.3780	Toxoplasma gondii serological reagents	2	Toxoplasma gondii serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies toToxoplasma gondii in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identifyToxoplasma gondii from clinical specimens. The identification aids in the diagnosis of toxoplasmosis caused by the parasitic protozoanToxoplasma gondii and provides epidemiological information on this disease. Congenital toxoplasmosis is characterized by lesions of the central nervous system, which if undetected and untreated may lead to brain defects, blindness, and death of an unborn fetus. The disease is characterized in children by inflammation of the brain and spinal cord.
C.3820	Treponema pallidum nontreponemal test reagents	2	Treponema pallidum nontreponemal test reagents are devices that consist of antigens derived from nontreponemal sources (sources not directly associated with treponemal organisms) and control sera (standardized sera with which test results are compared) used in serological tests to identify reagin, an antibody-like agent, which is produced from the reaction of treponema microorganisms with body tissues. The identification aids in the diagnosis of syphilis caused by microorganisms belonging to the genusTreponema and provides epidemiological information on syphilis.

C.3830	Treponema pallidum treponemal test reagents	2	Treponema pallidum treponemal test reagents are devices that consist of the antigens, antisera and all control reagents (standardized reagents with which test results are compared) which are derived from treponemal sources and that are used in the fluorescent treponemal antibody absorption test (FTA-ABS), theTreponema pallidum immobilization test (T.P.I.), and other treponemal tests used to identify antibodies toTreponema pallidum directly from infecting treponemal organisms in serum. The identification aids in the diagnosis of syphilis caused by bacteria belonging to the genusTreponema and provides epidemiological information on syphilis.
C.3850	Trichinella spiralis serological reagents	1	Trichinella spiralis serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies toTrichinella spiralis in serum. The identification aids in the diagnosis of trichinosis caused by parasitic roundworms belonging to the genusTrichinella and provides epidemiological information on trichinosis. Trichinosis is caused by ingestion of undercooked, infested meat, especially pork, and characterized by fever, muscle weakness, and diarrhea.
C.3860	Trichomonas vaginalis nucleic acid assay	2	A Trichomonas vaginalis nucleic acid assay is a device that consists of primers, probes, enzymes, and controls for the amplification and detection of trichomonas nucleic acids in endocervical swabs, vaginal swabs, and female urine specimens, from women symptomatic for vaginitis, cervicitis, or urethritis and/or to aid in the diagnosis of trichomoniasis in asymptomatic women. The detection of trichomonas nucleic acids, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of trichomoniasis caused by Trichomonas vaginalis.
C.3870	Trypanosoma spp. serological reagents	1	Trypanosoma spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies toTrypanosoma spp. in serum. The identification aids in the diagnosis of trypanosomiasis, a disease caused by parasitic protozoans belonging to the genusTrypanosoma. Trypanosomiasis in adults is a chronic disease characterized by fever, chills, headache, and vomiting. Central nervous system involvement produces typical sleeping sickness syndrome: physical exhaustion, inability to eat, tissue wasting, and eventual death. Chagas disease, an acute form of trypanosomiasis in children, most seriously affects the central nervous system and heart muscle.
C.3900	Varicella-zoster virus serological reagents	2	Varicella-zoster virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to varicella-zoster in serum. The identification aids in the diagnosis of diseases caused by varicella-zoster viruses and provides epidemiological information on these diseases. Varicella (chicken pox) is a mild, highly infectious disease, chiefly of children. Zoster (shingles) is the recurrent form of the disease, occurring in adults who were previously infected with varicella-zoster viruses. Zoster is the response (characterized by a rash) of the partially immune host to a reactivation of varicella viruses present in latent form in the patient's body.

C.3930	Vibrio cholerae serological reagents	1	Vibrio cholerae serological reagents are devices that are used in the agglutination (an antigen-antibody clumping reaction) test to identifyVibrio cholerae from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of cholera caused by the bacteriumVibrio cholerae and provides epidemiological information on cholera. Cholera is an acute infectious disease characterized by severe diarrhea with extreme fluid and electrolyte (salts) depletion, and by vomiting, muscle cramps, and prostration. If untreated, the severe dehydration may lead to shock, renal failure, cardiovascular collapse, and death.
C.3940	West nile virus serological reagents	2	West Nile virus serological reagents are devices that consist of antigens and antisera for the detection of anti-West Nile virus IgM antibodies, in human serum, from individuals who have signs and symptoms consistent with viral meningitis/encephalitis. The detection aids in the clinical laboratory diagnosis of viral meningitis/encephalitis caused by West Nile virus.
C.3945	Dengue virus serological reagents	2	Dengue virus serological reagents are devices that consist of antigens and antibodies for the detection of dengue virus and dengue antibodies in individuals who have signs and symptoms of dengue fever or dengue hemorrhagic fever. The detection aids in the clinical laboratory diagnosis of dengue fever or dengue hemorrhagic fever caused by dengue virus.
C.3946	Dengue virus nucleic acid amplification test reagents	2	Dengue virus nucleic acid amplification test reagents are devices that consist of primers, probes, enzymes, and controls for the amplification and detection of dengue virus serotypes 1, 2, 3, or 4 from viral ribonucleic acid (RNA) in human serum and plasma from individuals who have signs and symptoms consistent with dengue (mild or severe). The identification of dengue virus serotypes 1, 2, 3, or 4 in human serum and plasma (sodium citrate) collected from human patients with dengue provides epidemiologic information for surveillance of circulating dengue viruses.
C.3950	In vitro human immunodeficiency virus (HIV) drug resistance genotype assay	2	The in vitro HIV drug resistance genotype assay is a device that consists of nucleic acid reagent primers and probes together with software for predicting drug resistance/susceptibility based on results obtained with these primers and probes. It is intended for use in detecting HIV genomic mutations that confer resistance to specific antiretroviral drugs, as an aid in monitoring and treating HIV infection.
C.3970	Device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid	2	A device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid is a qualitative in vitro device intended for the detection and identification of microbial-associated nucleic acid sequences from patients suspected of meningitis or encephalitis. A device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid is intended to aid in the diagnosis of meningitis or encephalitis when used in conjunction with clinical signs and symptoms and other clinical and laboratory findings.

C.3980	Respiratory viral panel multiplex nucleic acid assay	2	A respiratory viral panel multiplex nucleic acid assay is a qualitative in vitro diagnostic device intended to simultaneously detect and identify multiple viral nucleic acids extracted from human respiratory specimens or viral culture. The detection and identification of a specific viral nucleic acid from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection when used in conjunction with other clinical and laboratory findings. The device is intended for detection and identification of a combination of the following viruses: (1) Influenza A and Influenza B; (2) Influenza A subtype H1 and Influenza A subtype H3; (3) Respiratory Syncytial Virus subtype A and Respiratory Syncytial Virus subtype B; (4) Parainfluenza 1, Parainfluenza 2, and Parainfluenza 3 virus; (5) Human Metapneumovirus; (6) Rhinovirus; and (7) Adenovirus.
C.3985	Device to detect and identify microorganisms and associated resistance marker nucleic acids directly in respiratory specimens	2	A device to detect and identify microorganisms and associated resistance marker nucleic acids directly from respiratory specimens is an in vitro diagnostic device intended for the detection and identification of microorganisms and associated resistance markers in respiratory specimens collected from patients with signs or symptoms of respiratory infection. The device is intended to aid in the diagnosis of respiratory infection in conjunction with clinical signs and symptoms and other laboratory findings. These devices do not provide confirmation of antibiotic susceptibility since mechanisms of resistance may exist other than those detected by the device.
C.3990	Gastrointestinal microorganism multiplex nucleic acid-based assay	2	A gastrointestinal microorganism multiplex nucleic acid-based assay is a qualitative in vitro diagnostic device intended to simultaneously detect and identify multiple gastrointestinal microbial nucleic acids extracted from human stool specimens. The device detects specific nucleic acid sequences for organism identification as well as for determining the presence of toxin genes. The detection and identification of a specific gastrointestinal microbial nucleic acid from individuals exhibiting signs and symptoms of gastrointestinal infection aids in the diagnosis of gastrointestinal infection when used in conjunction with clinical evaluation and other laboratory findings. A gastrointestinal microorganism multiplex nucleic acid-based assay also aids in the detection and identification of acute gastroenteritis in the context of outbreaks.

C.4070	RNA Preanalytical Systems.	1,2	RNA Preanalytical Systems are devices intended to collect, store, and transport patient specimens, and stabilize intracellular RNA from the specimens, for subsequent isolation and purification of the intracellular RNA for RT-PCR used in in vitro molecular diagnostic testing. Classification:(1) Class 1: Automatic specimen processing equipment. (2) Class 2: Reagents for isolation and purification.
C.4100	Complement reagent	1	A complement reagent is a device that consists of complement, a naturally occurring serum protein from any warm-blooded animal such as guinea pigs, that may be included as a component part of serological test kits used in the diagnosis of disease.
C.4500	Immunoelectrophoresis equipment	1	Immunoelectrophoresis equipment for clinical use with its electrical power supply is a device used for separating protein molecules. Immunoelectrophoresis is a procedure in which a complex protein mixture is placed in an agar gel and the various proteins are separated on the basis of their relative mobilities under the influence of an electric current. The separated proteins are then permitted to diffuse through the agar toward a multispecific antiserum, allowing precipitation and visualization of the separate complexes.
C.4520	Immunofluorometer equipment	1	Immunofluorometer equipment for clinical use with its electrical power supply is a device used to measure the fluorescence of fluorochrome-labeled antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light is passed through a solution in which a fluorochrome has been selectively attached to serum protein antibody molecules in suspension. The amount of light emitted by the fluorochrome label is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the fluorescence value and is used to measure the concentration of antigen-antibody complexes.
C.4540	Immunonephelometer equipment	1	Immunonephelometer equipment for clinical use with its electrical power supply is a device that measures light scattering from antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light passed through a solution is scattered by the particles in suspension. The amount of light is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the light-scattering value and is used to measure the concentration of antigen-antibody complexes. This generic type of device includes devices with various kinds of light sources, such as laser equipment.
C.4600	Ouchterlony agar plate	1	An ouchterlony agar plate for clinical use is a device containing an agar gel used to examine antigen-antibody reactions. In immunodiffusion, antibodies and antigens migrate toward each other through gel which originally contained neither of these reagents. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and is immobilized.

C.4700	Automated fluorescence in situ hybridization (FISH) enumeration systems.	2	An automated FISH enumeration system is a device that consists of an automated scanning microscope, image analysis system, and customized software applications for FISH assays. This device is intended for in vitro diagnostic use with FISH assays as an aid in the detection, counting and classification of cells based on recognition of cellular color, size, and shape, and in the detection and enumeration of FISH signals in interphase nuclei of formalin-fixed, paraffin-embedded human tissue specimens.
C.4750	Automated indirect immunofluorescence microscope and software-assisted system	2	An automated indirect immunofluorescence microscope and software-assisted system is a device that acquires, analyzes, stores, and displays digital images of indirect immunofluorescent slides. It is intended to be used as an aid in the determination of antibody status in clinical samples. The device may include a fluorescence microscope with light source, a motorized microscope stage, dedicated instrument controls, a camera, a computer, a sample processor, or other hardware components. The software may include fluorescent signal acquisition and processing software, data storage and transferring mechanisms, or assay specific algorithms to suggest results. A trained operator must confirm results generated with the device.
C.4800	Radial immunodiffusion plate	1	A radial immunodiffusion plate for clinical use is a device that consists of a plastic plate to which agar gel containing antiserum is added. In radial immunodiffusion, antigens migrate through gel which originally contains specific antibodies. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and immobilized.
C.4830	Rocket immunoelectrophoresis equipment	1	Rocket immunoelectrophoresis equipment for clinical use is a device used to perform a specific test on proteins by using a procedure called rocket immunoelectrophoresis. In this procedure, an electric current causes the protein in solution to migrate through agar gel containing specific antisera. The protein precipitates with the antisera in a rocket-shaped pattern, giving the name to the device. The height of the peak (or the area under the peak) is proportional to the concentration of the protein.
C.5040	Albumin immunological test system	1	An albumin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the albumin (a plasma protein) in serum and other body fluids. Measurement of albumin aids in the diagnosis of kidney and intestinal diseases.
C.5060	Prealbumin immunological test system	1	A prealbumin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the prealbumin (a plasma protein) in serum and other body fluids. Measurement of prealbumin levels in serum may aid in the assessment of the patient's nutritional status.
C.5065	Human allotypic marker immunological test system	1	A human allotypic marker immunological test system is a device that consists of the reagents used to identify by immunochemical techniques the inherited human protein allotypic markers (such as nGm, nA2m, and Km allotypes) in serum and other body fluids. The identification may be used while studying population genetics.

C.5080	Alpha-1-antichymotrypsin immunological test system	2	Analpha -1-antichymotrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniquesalpha -1-antichymotrypsin (a protein) in serum, other body fluids, and tissues.Alpha -1-antichymotrypsin helps protect tissues against proteolytic (protein-splitting) enzymes released during infection.
C.5090	Antimitochondrial antibody immunological test system	2	An antimitochondrial antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the antimitochondrial antibodies in human serum. The measurements aid in the diagnosis of diseases that produce a spectrum of autoantibodies (antibodies produced against the body's own tissue), such as primary biliary cirrhosis (degeneration of liver tissue) and chronic active hepatitis (inflammation of the liver).
C.5100	Antinuclear antibody immunological test system	2	An antinuclear antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum, other body fluids, and tissues that react with cellular nuclear constituents (molecules present in the nucleus of a cell, such as ribonucleic acid, deoxyribonucleic acid, or nuclear proteins). The measurements aid in the diagnosis of systemic lupus erythematosus (a multisystem autoimmune disease in which antibodies attack the victim's own tissues), hepatitis (a liver disease), rheumatoid arthritis, Sjogren's syndrome (arthritis with inflammation of the eye, eyelid, and salivary glands), and systemic sclerosis (chronic hardening and shrinking of many body tissues).
C.5110	Antiparietal antibody immunological test system	2	An antiparietal antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific antibody for gastric parietal cells in serum and other body fluids. Gastric parietal cells are those cells located in the stomach that produce a protein that enables vitamin B12to be absorbed by the body. The measurements aid in the diagnosis of vitamin B12deficiency (or pernicious anemia), atrophic gastritis (inflammation of the stomach), and autoimmune connective tissue diseases (diseases resulting when the body produces antibodies against its own tissues).
C.5120	Antismooth muscle antibody immunological test system	2	An antismooth muscle antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the antismooth muscle antibodies (antibodies to nonstriated, involuntary muscle) in serum. The measurements aid in the diagnosis of chronic hepatitis (inflammation of the liver) and autoimmune connective tissue diseases (diseases resulting from antibodies produced against the body's own tissues).
C.5130	Alpha-1-antitrypsin immunological test system	2	Analpha -1-antitrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques thealpha -1-antitrypsin (a plasma protein) in serum, other body fluids, and tissues. The measurements aid in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition,alpha -1-antitrypsin deficiency has been associated with pulmonary emphysema.

C.5150	Bence-Jones proteins immunological test system	2	A Bence-Jones proteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Bence-Jones proteins in urine and plasma. Immunoglobulin molecules normally consist of pairs of polypeptide chains (subunits) of unequal size (light chains and heavy chains) bound together by several disulfide bridges. In some cancerous conditions, there is a proliferation of one plasma cell (antibody-producing cell) with excess production of light chains of one specific kind (monoclonal light chains). These free homogeneous light chains not associated with an immunoglobulin molecule can be found in urine and plasma, and have been called Bence-Jones proteins. Measurement of Bence-Jones proteins and determination that they are monoclonal aid in the diagnosis of multiple myeloma (malignant proliferation of plasma cells), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins by spleen and bone marrow cells), leukemia (cancer of the blood-forming organs), and lymphoma (cancer of the lymphoid tissue).
C.5160	Beta-globulin immunological test system	1	Abeta -globulin immunological test system is a device that consists of reagents used to measure by immunochemical techniques beta globulins (serum protein) in serum and other body fluids.Beta -globulin proteins includebeta -lipoprotein, transferrin, glycoproteins, and complement, and are rarely associated with specific pathologic disorders.
C.5170	Breast milk immunological test system	1	A breast milk immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the breast milk proteins.
C.5180	Fecal calprotectin immunological test system	2	A fecal calprotectin immunological test system is anin vitro diagnostic device that consists of reagents used to quantitatively measure, by immunochemical techniques, fecal calprotectin in human stool specimens. The device is intended forin vitro diagnostic use as an aid in the diagnosis of inflammatory bowel diseases (IBD), specifically Crohn's disease and ulcerative colitis, and as an aid in differentiation of IBD from irritable bowel syndrome.
C.5200	Carbonic anhydrase B and C immunological test system	1	A carbonic anhydrase B and C immunological test system is a device that consists of the reagents used to measure by immunochemical techniques specific carbonic anhydrase protein molecules in serum and other body fluids. Measurements of carbonic anhydrase B and C aid in the diagnosis of abnormal hemoglobin metabolism.
C.5210	Ceruloplasmin immunological test system	2	A ceruloplasmin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the ceruloplasmin (copper-transporting serum protein) in serum, other body fluids, or tissues. Measurements of ceruloplasmin aid in the diagnosis of copper metabolism disorders.

C.5220	Cohn fraction II immunological test system	1	A Cohn fraction II immunological test system is a device that consists of the reagents that contain or are used to measure that fraction of plasma containing protein gamma globulins, predominantly of the IgG class. The device may be used as a coprecipitant in radioimmunoassay methods, as raw material for the purification of IgG subclasses, and to reduce nonspecific adsorption of plasma proteins in immunoassay techniques. Measurement of these proteins aids in the diagnosis of any disease concerned with abnormal levels of IgG gamma globulins such as agammaglobulinemia or multiple myeloma.
C.5230	Colostrum immunological test system	1	A colostrum immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific proteins in colostrum. Colostrum is a substance excreted by the mammary glands during pregnancy and until production of breast milk begins 1 to 5 days after childbirth.
C.5240	Complement components immunological test system	2	A complement components immunological test system is a device that consists of the reagents used to measure by immunochemical techniques complement components C1q, C1r, C1s, C2, C3, C4, C5, C6, C7, C8, and C9, in serum, other body fluids, and tissues. Complement is a group of serum proteins which destroy infectious agents. Measurements of these proteins aids in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.
C.5250	Complement C1 inhibitor (inactivator) immunological test system	2	A complement C1inhibitor (inactivator) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C1inhibitor (a plasma protein) in serum. Complement C1inhibitor occurs normally in plasma and blocks the action of the C1component of complement (a group of serum proteins which destroy infectious agents). Measurement of complement C1inhibitor aids in the diagnosis of hereditary angioneurotic edema (increased blood vessel permeability causing swelling of tissues) and a rare form of angioedema associated with lymphoma (lymph node cancer).
C.5260	Complement C3b inactivator immunological test system	2	A complement C3binactivator immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C3binactivator (a plasma protein) in serum. Complement is a group of serum proteins that destroy infectious agents. Measurement of complement C3binactivator aids in the diagnosis of inherited antibody dysfunction.
C.5270	C-reactive protein immunological test system	2	A C-reactive protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the C-reactive protein in serum and other body fluids. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.

C.5320	Properdin factor B immunological test system	1	A properdin factor B immunological test system is a device that consists of the reagents used to measure by immunochemical techniques properdin factor B in serum and other body fluids. The deposition of properdin factor B in body tissues or a corresponding depression in the amount of properdin factor B in serum and other body fluids is evidence of the involvement of the alternative to the classical pathway of activation of complement (a group of plasma proteins which cause the destruction of cells which are foreign to the body). Measurement of properdin factor B aids in the diagnosis of several kidney diseases, e.g., chronic glomerulonephritis (inflammation of the glomeruli of the kidney), lupus nephritis (kidney disease associated with a multisystem autoimmune disease, systemic lupus erythematosus), as well as several skin diseases, e.g., dermititis herpetiformis (presence of vesicles on the skin that burn and itch), and pemphigus vulgaris (large vesicles on the skin). Other diseases in which the alternate pathway of complement activation has been implicated include rheumatoid arthritis, sickle cell anemia, and gram-negative bacteremia.
C.5330	Factor XIII, A, S, immunological test system	1	A factor XIII, A, S, immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the factor XIII (a bloodclotting factor), in platelets (A) or serum (S). Measurements of factor XIII, A, S, aid in the diagnosis and treatment of certain bleeding disorders resulting from a deficiency of this factor.
C.5340	Ferritin immunological test system	2	A ferritin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the ferritin (an iron-storing protein) in serum and other body fluids. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency amemia.
C.5350	Fibrinopeptide A immunological test system	2	A fibrinopeptide A immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the fibrinopeptide A (a blood-clotting factor) in plasma and other body fluids. Measurement of fibrinopeptide A may aid in the diagnosis and treatment of certain blood-clotting disorders.
C.5360	Cohn fraction IV immunological test system	1	A Cohn fraction IV immunological test system is a device that consists of or measures that fraction of plasma proteins, predominantlyalpha- andbeta- globulins, used as a raw material for the production of purealpha- orbeta-globulins. Measurement of specificalpha- orbeta- globulins aids in the diagnosis of many diseases, such as Wilson's disease (an inherited disease affecting the liver and brain), Tangier's disease (absence ofalpha- 1-lipoprotein), malnutrition, iron deficiency anemia, red blood cell disorders, and kidney disease.
C.5370	Cohn fraction V immunological test system	1	A Cohn fraction V immunological test system is a device that consists of or measures that fraction of plasma containing predominantly albumin (a plasma protein). This test aids in the diagnosis of diseases where albumin levels may be depressed, e.g., nephrosis (disease of the kidney), proteinuria (protein in the urine), gastroenteropathy (disease of the stomach and small intestine), rheumatoid arthritis, and viral hepatitis.

C.5380	Free secretory component immunological test system	1	A free secretory component immunological test system is a device that consists of the reagents used to measure by immunochemical techniques free secretory component (normally a portion of the secretory IgA antibody molecule) in body fluids. Measurement of free secretory component (protein molecules) aids in the diagnosis or repetitive lung infections and other hypogammaglobulinemic conditions (low antibody levels).
C.5400	Alpha-globulin immunological test system	1	Analpha- globulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques thealpha- globulin (a serum protein) in serum and other body fluids. Measurement ofalpha- globulin may aid in the diagnosis of inflammatory lesions, infections, severe burns, and a variety of other conditions.
C.5420	Alpha-1-glycoproteins immunological test system	1	Analpha- 1-glycoproteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniquesalpha- 1-glycoproteins (a group of plasma proteins found in thealpha- 1 group when subjected to electrophoresis) in serum and other body fluids. Measurement of specificalpha- 1-glycoproteins may aid in the diagnosis of collagen (connective tissue) disorders, tuberculosis, infections, extensive malignancy, and diabetes.
C.5425	Alpha-2-glycoproteins immunological test system	1	Analpha -2-glycoproteins immunolgical test system is a device that consists of the reagents used to measure by immunochemical techniques thealpha -2-glycoproteins (a group of plasma proteins found in thealpha- 2 group when subjected to electrophoresis) in serum and other body fluids. Measurement ofalpha -2-glycoproteins aids in the diagnosis of some cancers and genetically inherited deficiencies of these plasma proteins.
C.5430	Beta-2-glycoprotein I immunological test system	1	Abeta -2-glycoprotein I immunological test system is a device that consists of the reagents used to measure by immunochemical techniques thebeta -2-glycoprotein I (a serum protein) in serum and other body fluids. Measurement ofbeta -2-glycoprotein I aids in the diagnosis of an inherited deficiency of this serum protein.
C.5440	Beta-2-glycoprotein III immunological test system	1	Abeta -2-glycoprotein III immunological test system is a device that consists of the reagents used to measure by immunochemical techniques thebeta -2-glycoprotein III (a serum protein) in serum and other body fluids. Measurement ofbeta -2-glycoprotein III aids in the diagnosis of an inherited deficiency of this serum protein and a variety of other conditions.
C.5460	Haptoglobin immunological test system	1	A haptoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the haptoglobin (a protein that binds hemoglobin, the oxygen-carrying pigment in red blood cells) in serum. Measurement of haptoglobin may aid in the diagnosis of hemolytic diseases (diseases in which the red blood cells rupture and release hemoglobin) related to the formation of hemoglobin-haptoglobin complexes and certain kidney diseases.

C.5470	Hemoglobin immunological test system	2	A hemoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the different types of free hemoglobin (the oxygen-carrying pigment in red blood cells) in blood, urine, plasma, or other body fluids. Measurements of free hemoglobin aid in the diagnosis of various hematologic disorders, such as sickle cell anemia, Fanconi's anemia (a rare inherited disease), aplastic anemia (bone marrow does not produce enough blood cells), and leukemia (cancer of the blood-forming organs).
C.5490	Hemopexin immunological test system	1	A hemopexin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the hemopexin (a serum protein that binds heme, a component of hemoglobin) in serum. Measurement of hemopexin aids in the diagnosis of various hematologic disorders, such as hemolytic anemia (anemia due to shortened in vivo survival of mature red blood cells and inability of the bone marrow to compensate for their decreased life span) and sickle cell anemia.
C.5500	Hypersensitivity pneumonitis immunological test system	2	A hypersensitivity pneumonitis immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the immunoglobulin antibodies in serum which react specifically with organic dust derived from fungal or animal protein sources. When these antibodies react with such dusts in the lung, immune complexes precipitate and trigger an inflammatory reaction (hypersensitivity pneumonitis). Measurement of these immunoglobulin G antibodies aids in the diagnosis of hypersensitivity pneumonitis and other allergic respiratory disorders.
C.5510	Immunoglobulins A, G, M, D, and E immunological test system	2	An immunoglobulins A, G, M, D, and E immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the immunoglobulins A, G, M, D, an E (serum antibodies) in serum. Measurement of these immunoglobulins aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.
C.5520	Immunoglobulin G (Fab fragment specific) immunological test system	1	An immunoglobulin G (Fab fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Fab antigen-binding fragment resulting from breakdown of immunoglobulin G antibodies in urine, serum, and other body fluids. Measurement of Fab fragments of immunoglobulin G aids in the diagnosis of lymphoproliferative disorders, such as multiple myeloma (tumor of bone marrow cells), Waldenstrom's macroglobulinemia (increased immunoglobulin production by the spleen and bone marrow cells), and lymphoma (tumor of the lymphoid tissues).
C.5530	Immunoglobulin G (Fc fragment specific) immunological test system	1	An immunoglobulin G (Fc fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Fc (carbohydrate containing) fragment of immunoglobulin G (resulting from breakdown of immunoglobulin G antibodies) in urine, serum, and other body fluids. Measurement of immunoglobulin G Fc fragments aids in the diagnosis of plasma cell antibody-forming abnormalities, e.g., gamma heavy chain disease.

C.5540	Immunoglobulin G (Fd fragment specific) immunological test system	1	An immunoglobulin G (Fd fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the amino terminal (antigen-binding) end (Fd fragment) of the heavy chain (a subunit) of the immunoglobulin antibody molecule in serum. Measurement of immunoglobulin G Fd fragments aids in the diagnosis of plasma antibody-forming cell abnormalities.
C.5550	Immunoglobulin (light chain specific) immunological test system	2	An immunoglobulin (light chain specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques both kappa and lambda types of light chain portions of immunoglobulin molecules in serum, other body fluids, and tissues. In some disease states, an excess of light chains are produced by the antibody-forming cells. These free light chains, unassociated with gamma globulin molecules, can be found in a patient's body fluids and tissues. Measurement of the various amounts of the different types of light chains aids in the diagnosis of multiple myeloma (cancer of antibody-forming cells), lymphocytic neoplasms (cancer of lymphoid tissue), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins), and connective tissue diseases such as rheumatoid arthritis or systemic lupus erythematosus.
C.5560	Lactic dehydrogenase immunological test system	1	A lactic dehydrogenase immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the activity of the lactic dehydrogenase enzyme in serum. Increased levels of lactic dehydrogenase are found in a variety of conditions, including megaloblastic anemia (decrease in the number of mature red blood cells), myocardial infarction (heart disease), and some forms of leukemia (cancer of the blood-forming organs). However, the diagnostic usefulness of this device is limited because of the many conditions known to cause increased lactic dehydrogenase levels.
C.5570	Lactoferrin immunological test system	1	A lactoferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the lactoferrin (an iron-binding protein with the ability to inhibit the growth of bacteria) in serum, breast milk, other body fluids, and tissues. Measurement of lactoferrin may aid in the diagnosis of an inherited deficiency of this protein.
C.5580	Alpha-1-lipoprotein immunological test system	2	Analpha -1-lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques thealpha- 1-lipoprotein (high-density lipoprotein) in serum and plasma. Measurement ofalpha- 1-lipoprotein may aid in the diagnosis of Tangier disease (a hereditary disorder of fat metabolism).
C.5590	Lipoprotein X immunological test system	1	A lipoprotein X immunological test system is a device that consists of the reagents used to measure by immunochemical techniques lipoprotein X (a high-density lipoprotein) in serum and other body fluids. Measurement of lipoprotein X aids in the diagnosis of obstructive liver disease.

C.5600	Low-density lipoprotein immunological test system	2	A low-density lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the low-density lipoprotein in serum and other body fluids. Measurement of low-density lipoprotein in serum may aid in the diagnosis of disorders of lipid (fat) metabolism and help to identify young persons at risk from cardiovascular diseases.
C.5620	Alpha-2-macroglobulin immunological test system	2	Analpha -2-macroglobulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques thealpha -2-macroglobulin (a serum protein) in plasma. Measurement ofalpha -2-macroglobulin may aid in the diagnosis of blood-clotting or clot lysis disorders.
C.5630	Beta-2-microglobulin immunological test system	2	Abeta -2-microglobulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniquesbeta -2-microglobulin (a protein molecule) in serum, urine, and other body fluids. Measurement ofbeta -2-microglobulin aids in the diagnosis of active rheumatoid arthritis and kidney disease.
C.5640	Infectious mononucleosis immunological test system	2	An infectious mononucleosis immunological test system is a device that consists of the reagents used to measure by immunochemical techniques heterophile antibodies frequently associated with infectious mononucleosis in serum, plasma, and other body fluids. Measurements of these antibodies aid in the diagnosis of infectious mononucleosis.
C.5660	Multiple autoantibodies immunological test system	2	A multiple autoantibodies immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoantibodies (antibodies produced against the body's own tissues) in serum and other body fluids. Measurement of multiple autoantibodies aids in the diagnosis of autoimmune disorders (disease produced when the body's own tissues are injured by autoantibodies).
C.5665	Aquaporin-4 autoantibody immunological test system	2	An Aquaporin-4 autoantibody immunological test system is a device that consists of reagents used to measure by immunochemical techniques autoantibodies in human serum samples that react with Aquaporin-4 (AQP4Ab). The measurements aid in the diagnosis of neuromyelitis optica (NMO) and neuromyelitis optica spectrum disorders (NMOSD) in conjunction with other clinical, laboratory, and radiological (e.g., magnetic resonance imaging) findings.
C.5670	Zinc transporter 8 autoantibody immunological test system	2	A zinc transporter 8 autoantibody immunological test system is a device that consists of reagents used to measure, by immunochemical techniques, the autoantibodies in human serum samples that react with Zinc Transporter 8 (ZnT8). The measurements aid in the diagnosis of Type 1 diabetes mellitus (autoimmune mediated diabetes) in conjunction with other clinical and laboratory findings.
C.5680	Myoglobin immunological test system	2	A myoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the myoglobin (an oxygen storage protein found in muscle) in serum and other body fluids. Measurement of myoglobin aids in the rapid diagnosis of heart or renal disease.

C.5700	Whole human plasma or serum immunological test system	1	A whole human plasma or serum immunological test system is a device that consists of reagents used to measure by immunochemical techniques the proteins in plasma or serum. Measurements of proteins in plasma or serum aid in the diagnosis of any disease concerned with abnormal levels of plasma or serum proteins, e.g., agammaglobulinemia, allergies, multiple myeloma, rheumatoid vasculitis, or hereditary angioneurotic edema.
C.5715	Plasminogen immunological test system	1	A plasminogen immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the plasminogen (an inactive substance from which plasmin, a blood-clotting factor, is formed) in serum, other body fluids, and tissues. Measurement of plasminogen levels may aid in the diagnosis of fibrinolytic (blood-clotting) disorders.
C.5735	Prothrombin immunological test system	1	A prothrombin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the prothrombin (clotting factor II) in serum. Measurements of the amount of antigenically competent (ability to react with protein antibodies) prothrombin aid in the diagnosis of blood-clotting disorders.
C.5750	Radioallergosorbent (RAST) immunological test system	2	A radioallergosorbent immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the allergen antibodies (antibodies which cause an allergic reaction) specific for a given allergen. Measurement of specific allergen antibodies may aid in the diagnosis of asthma, allergies, and other pulmonary disorders.
C.5760	Tryptase test system	2	A tryptase test system is a device that aids in the diagnosis of systemic mastocytosis. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of patients with a suspicion of systemic mastocytosis in conjunction with other clinical and laboratory findings.
C.5765	Retinol-binding protein immunological test system	1	A retinol-binding protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the retinol-binding protein that binds and transports vitamin A in serum and urine. Measurement of this protein may aid in the diagnosis of kidney disease and in monitoring patients with kidney transplants.
C.5775	Rheumatoid factor immunological test system	2	A rheumatoid factor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the rheumatoid factor (antibodies to immunoglobulins) in serum, other body fluids, and tissues. Measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis.
C.5785	Anti-Saccharomyces cerevisiae (S.cerevisiae) antibody (ASCA) test systems	2	The Anti-Saccharomyces cerevisiae (S. cerevisiae) antibody (ASCA) test system is an in vitro diagnostic device that consists of the reagents used to measure, by immunochemical techniques, antibodies toS. cerevisiae (baker's or brewer's yeast) in human serum or plasma. Detection ofS. cerevisiae antibodies may aid in the diagnosis of Crohn's disease.

C.5800	Seminal fluid (sperm) immunological test system	1	A seminal fluid (sperm) immunological test system is a device that consists of the reagents used for legal purposes to identify and differentiate animal and human semen. The test results may be used as court evidence in alleged instances of rape and other sex-related crimes.
C.5820	Systemic lupus erythematosus immunlogical test system	2	A systemic lupus erythematosus (SLE) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum and other body fluids that react with cellular nuclear double-stranded deoxyribonucleic acid (DNA) or other nuclear constituents that are specifically diagnostic of SLE. Measurement of nuclear double-stranded DNA antibodies aids in the diagnosis of SLE (a multisystem autoimmune disease in which tissues are attacked by the person's own antibodies).
C.5830	Brain trauma assessment test	2	A brain trauma assessment test is a device that consists of reagents used to detect and measure brain injury biomarkers in human specimens. The measurements aid in the evaluation of patients with suspected mild traumatic brain injury in conjunction with other clinical information to assist in determining the need for head imaging per current standard of care.
C.5860	Total spinal fluid immunological test system	1	A total spinal fluid immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the total protein in cerebrospinal fluid. Measurement of spinal fluid proteins may aid in the diagnosis of multiple sclerosis and other diseases of the nervous system.
C.5870	Thyroid autoantibody immunological test system	2	A thyroid autoantibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the thyroid autoantibodies (antibodies produced against the body's own tissues). Measurement of thyroid autoantibodies may aid in the diagnosis of certain thyroid disorders, such as Hashimoto's disease (chronic lymphocytic thyroiditis), nontoxic goiter (enlargement of thyroid gland), Grave's disease (enlargement of the thyroid gland with protrusion of the eyeballs), and cancer of the thyroid.
C.5880	Transferrin immunological test system	2	A transferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in serum, plasma, and other body fluids. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.
C.5890	Inter-alpha trypsin inhibitor immunological test system	1	An inter-alpha trypsin inhibitor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the inter-alpha trypsin inhibitor (a protein) in serum and other body fluids. Measurement of inter-alpha trypsin inhibitor may aid in the diagnosis of acute bacterial infection and inflammation.
C.5900	Cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation detection system.	2	The CFTR gene mutation detection system is a device used to simultaneously detect and identify a panel of mutations and variants in the CFTR gene. It is intended as an aid in confirmatory diagnostic testing of individuals with suspected cystic fibrosis (CF), carrier identification, and newborn screening. This device is not intended for stand-alone diagnostic purposes, prenatal diagnostic, pre-implantation, or population screening.

C.5930	Newborn screening test	2	A newborn screening test for SCID is a prescription device intended to measure T-cell receptor excision circle (TREC) DNA obtained from dried blood spot specimens on filter paper using a polymerase chain reaction based test as an aid in screening newborns for SCID. Presumptive positive results must be followed up by diagnostic confirmatory testing. This test is not intended for use as a diagnostic test, or for screening of SCID-like syndromes, such as DiGeorge syndrome or Omenn syndrome. It is also not intended to screen for less acute SCID syndromes, such as leaky SCID or variant SCID.
C.5940	Autosomal recessive carrier screening gene mutation detection system	2	Autosomal recessive carrier screening gene mutation detection system is a qualitative in vitro molecular diagnostic system used for genotyping of clinically relevant variants in genomic DNA isolated from human specimens intended for prescription use or over-the-counter use. The device is intended for autosomal recessive disease carrier screening in adults of reproductive age. The device is not intended for copy number variation, cytogenetic, or biochemical testing.
C.5950	Genetic health risk assessment system	2	A genetic health risk assessment system is a qualitative in vitro molecular diagnostic system used for detecting variants in genomic deoxyribonucleic acid (DNA) isolated from human specimens that will provide information to users about their genetic risk of developing a disease to inform lifestyle choices and/or conversations with a health care professional. This assessment system is for over-the-counter use. This device does not determine the person's overall risk of developing a disease.
C.6010	Tumor-associated antigen immunological test system	2	A tumor-associated antigen immunological test system is a device that consists of reagents used to qualitatively or quantitatively measure, by immunochemical techniques, tumor-associated antigens in serum, plasma, urine, or other body fluids. This device is intended as an aid in monitoring patients for disease progress or response to therapy or for the detection of recurrent or residual disease.
C.6020	Immunomagnetic circulating cancer cell selection and enumeration system	2	An immunomagnetic circulating cancer cell selection and enumeration system is a device that consists of biological probes, fluorochromes, and other reagents; preservation and preparation devices; and a semiautomated analytical instrument to select and count circulating cancer cells in a prepared sample of whole blood. This device is intended for adjunctive use in monitoring or predicting cancer disease progression, response to therapy, and for the detection of recurrent disease.
C.6030	AFP-L3% immunological test system.	2	An AFP-L3% immunological test system is an in vitro device that consists of reagents and an automated instrument used to quantitatively measure, by immunochemical techniques, AFP and AFP-L3 subfraction in human serum. The device is intended for in vitro diagnostic use as an aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma, in conjunction with other laboratory findings, imaging studies, and clinical assessment.

C.6040	Gene expression profiling test system for breast cancer prognosis	2	A gene expression profiling test system for breast cancer prognosis is a device that measures the ribonucleic acid (RNA) expression level of multiple genes and combines this information to yield a signature (pattern or classifier or index) to aid in prognosis of previously diagnosed breast cancer.
C.6050	Ovarian adnexal mass assessment score test system	2	An ovarian/adnexal mass assessment test system is a device that measures one or more proteins in serum or plasma. It yields a single result for the likelihood that an adnexal pelvic mass in a woman, for whom surgery is planned, is malignant. The test is for adjunctive use, in the context of a negative primary clinical and radiological evaluation, to augment the identification of patients whose gynecologic surgery requires oncology expertise and resources.Classification. Class II
C.6060	BCR-ABL quantitation test	2	A BCR-ABL quantitation test is identified as a reverse transcription-quantitative polymerase chain reaction (RT-qPCR) test for the quantitation of BCR-ABL1 expressed on the International Scale (IS) and control transcripts in total RNA from whole blood of diagnosed t(9;22) positive chronic myeloid leukemia (CML) patients during monitoring of treatment with tyrosine kinase inhibitors. This test is not intended for the diagnosis of CML.
C.6080	Next generation sequencing (NGS) based tumor profiling test	2	A next generation sequencing (NGS) based tumor profiling test is a qualitative in vitro diagnostic test intended for NGS analysis of tissue specimens from malignant solid neoplasms to detect somatic mutations in a broad panel of targeted genes to aid in the management of previously diagnosed cancer patients by qualified health care professionals.
C.9999	Others(Immunology and Microbiology Device)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.
D.1040	Powered algesimeter	2	A powered algesimeter is a device using electrical stimulation intended to determine a patient's sensitivity to pain after administration of an anesthetic agent.
D.1075	Argon gas analyzer	2	An argon gas analyzer is a device intended to measure the concentration of argon in a gas mixture to aid in determining the patient's ventilatory status. The device may use techniques such as mass spectrometry or thermal conductivity.
D.1100	Arterial blood sampling kit	1	An arterial blood sampling kit is a device, in kit form, used to obtain arterial blood samples from a patient for blood gas determinations. The kit may include a syringe, needle, cork, and heparin.
D.1120	Indwelling blood oxyhemoglobin concentration analyzer	3	An indwelling blood oxyhemoglobin concentration analyzer is a photoelectric device used to measure, in vivo, the oxygen-carrying capacity of hemoglobin in blood to aid in determining the patient's physiological status.
D.1150	Indwelling blood carbon dioxide partial pressure (Pco2) analyzer	2	An indwelling blood carbon dioxide partial pressure PCO2analyzer is a device that consists of a catheter-tip PCO2transducer (e.g., PCO2electrode) and that is used to measure, in vivo, the partial pressure of carbon dioxide in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

D.1170	Indwelling blood hydrogen ion concentration (pH) analyzer	2	An indwelling blood hydrogen ion concentration (pH) analyzer is a device that consists of a catheter-tip pH electrode and that is used to measure, in vivo, the hydrogen ion concentration (pH) in blood to aid in determining the patient's acid-base balance.
D.1200	Indwelling blood oxygen partial pressure (Po2) analyzer	2	An indwelling blood oxygen partial pressure (PO2) analyzer is a device that consists of a catheter-tip PO2transducer (e.g., PO2electrode) and that is used to measure, in vivo, the partial pressure of oxygen in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.
D.1400	Carbon dioxide gas analyzer	2	A carbon dioxide gas analyzer is a device intended to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory, circulatory, and metabolic status. The device may use techniques such as chemical titration, absorption of infrared radiation, gas chromatography, or mass spectrometry.
D.1430	Carbon monoxide gas analyzer	2	A carbon monoxide gas analyzer is a device intended to measure the concentration of carbon monoxide in a gas mixture to aid in determining the patient's ventilatory status. The device may use techniques such as infrared absorption or gas chromatography.
D.1500	Enflurane gas analyzer	2	An enflurane gas analyzer is a device intended to measure the concentration of enflurane anesthetic in a gas mixture.
D.1575	Gas collection vessel	1	A gas collection vessel is a container-like device intended to collect a patient's exhaled gases for subsequent analysis. It does not include a sampling pump.
D.1620	Halothane gas analyzer	2	A halothane gas analyzer is a device intended to measure the concentration of halothane anesthetic in a gas mixture. The device may use techniques such as mass spectrometry or absorption of infrared or ultraviolet radiation.
D.1640	Helium gas analyzer	2	A helium gas analyzer is a device intended to measure the concentration of helium in a gas mixture during pulmonary function testing. The device may use techniques such as thermal conductivity, gas chromatography, or mass spectrometry.
D.1670	Neon gas analyzer	2	A neon gas analyzer is a device intended to measure the concentration of neon in a gas mixture exhaled by a patient. The device may use techniques such as mass spectrometry or thermal conductivity.
D.1690	Nitrogen gas analyzer	2	A nitrogen gas analyzer is a device intended to measure the concentration of nitrogen in respiratory gases to aid in determining a patient's ventilatory status. The device may use techniques such as gas chromatography or mass spectrometry.
D.1700	Nitrous oxide gas analyzer	2	A nitrous oxide gas analyzer is a device intended to measure the concentration of nitrous oxide anesthetic in a gas mixture. The device may use techniques such as infrared absorption or mass spectrometry.

D.1720	Oxygen gas analyzer	2	An oxygen gas analyzer is a device intended to measure the concentration of oxygen in respiratory gases by techniques such as mass spectrometry, polarography, thermal conductivity, or gas chromatography. This generic type of device also includes paramagnetic analyzers.
D.1730	Oxygen uptake computer	2	An oxygen uptake computer is a device intended to compute the amount of oxygen consumed by a patient and may include components for determining expired gas volume and composition.
D.1750	Pressure plethysmograph	2	A pressure plethysmograph is a device used to determine a patient's airway resistance and lung volumes by measuring pressure changes while the patient is in an airtight box.
D.1760	Volume plethysmograph	2	A volume plethysmograph is an airtight box, in which a patient sits, that is used to determine the patient's lung volume changes.
D.1780	Inspiratory airway pressure meter	2	An inspiratory airway pressure meter is a device used to measure the amount of pressure produced in a patient's airway during maximal inspiration.
D.1800	Rhinoanemometer	2	A rhinoanemometer is a device used to quantify the amount of nasal congestion by measuring the airflow through, and differential pressure across, a patient's nasal passages.
D.1840	Diagnostic spirometer	2	A diagnostic spirometer is a device used in pulmonary function testing to measure the volume of gas moving in or out of a patient's lungs.
D.1850	Monitoring spirometer	2	A monitoring spirometer is a device used to measure continuously a patient's tidal volume (volume of gas inhaled by the patient during each respiration cycle) or minute volume (the tidal volume multiplied by the rate of respiration for 1 minute) for the evaluation of the patient's ventilatory status.
D.1860	Peak-flow meter for spirometry	2	A peak-flow meter for spirometry is a device used to measure a patient's maximum ventilatory flow rate.
D.1880	Pulmonary-function data calculator	2	A pulmonary-function data calculator is a device used to calculate pulmonary-function values based on actual physical data obtained during pulmonary-function testing.
D.1890	Predictive pulmonary-function value calculator	2	A predictive pulmonary-function value calculator is a device used to calculate normal pulmonary-function values based on empirical equations.
D.1900	Diagnostic pulmonary-function interpretation calculator	2	A diagnostic pulmonary-function interpretation calculator is a device that interprets pulmonary study data to determine clinical significance of pulmonary-function values.
D.1910	Esophageal stethoscope	1	An esophageal stethoscope is a nonpowered device that is inserted into a patient's esophagus to enable the user to listen to heart and breath sounds.
D.1920	Esophageal stethoscope with electrical conductors	2	An esophageal stethoscope with electrical conductors is a device that is inserted into the esophagus to listen to a patient's heart and breath sounds and to monitor electrophysiological signals. The device may also incorporate a thermistor for temperature measurement.

D.1930	Stethoscope head	1	A stethoscope head is a weighted chest piece used during anesthesia to listen to a patient's heart, breath, and other physiological sounds.
D.1975	Water vapor analyzer	1	A water vapor analyzer is a device intended to measure the concentration of water vapor in a patient's expired gases by using techniques such as mass spectrometry.
D.2025	Ultrasonic air embolism monitor	2	An ultrasonic air embolism monitor is a device used to detect air bubbles in a patient's blood stream. It may use Doppler or other ultrasonic principles.
D.2300	Bourdon gauge flowmeter	1	A bourdon gauge flowmeter is a device intended for medical purposes that is used in conjunction with respiratory equipment to sense gas pressure. The device is calibrated to indicate gas flow rate when the outflow is open to the atmosphere.
D.2320	Uncompensated thorpe tube flowmeter	1	An uncompensated thorpe tube flowmeter is a device intended for medical purposes that is used to indicate and control gas flow rate accurately. The device includes a vertically mounted tube and is calibrated when the outlet of the flowmeter is open to the atmosphere.
D.2340	Compensated thorpe tube flowmeter	1	A compensated thorpe tube flowmeter is a device intended for medical purposes that is used to control and measure gas flow rate accurately. The device includes a vertically mounted tube, with the outlet of the flowmeter calibrated to a reference pressure.
D.2375	Breathing frequency monitor	2	A breathing (ventilatory) frequency monitor is a device intended to measure or monitor a patient's respiratory rate. The device may provide an audible or visible alarm when the respiratory rate, averaged over time, is outside operator settable alarm limits.
D.2377	Apnea monitor	2	An apnea monitor is a complete system intended to alarm primarily upon the cessation of breathing timed from the last detected breath. The apnea monitor also includes indirect methods of apnea detection such as monitoring of heart rate and other physiological parameters linked to the presence or absence of adequate respiration.
D.2380	Nitric oxide analyzer	2	The nitric oxide analyzer is a device intended to measure the concentration of nitric oxide in respiratory gas mixtures during administration of nitric oxide.
D.2385	Nitric dioxide analyzer	2	The nitrogen dioxide analyzer is a device intended to measure the concentration of nitrogen dioxide in respiratory gas mixtures during administration of nitric oxide.
D.2450	Lung water monitor	3	A lung water monitor is a device used to monitor the trend of fluid volume changes in a patient's lung by measuring changes in thoracic electrical impedance (resistance to alternating current) by means of electrodes placed on the patient's chest.

D.2480	Cutaneous carbon dioxide (PcCO2) monitor	2	A cutaneous carbon dioxide (PcCO2) monitor is a noninvasive heated sensor and a pH-sensitive glass electrode placed on a patient's skin, which is intended to monitor relative changes in a hemodynamically stable patient's cutaneous carbon dioxide tension as an adjunct to arterial carbon dioxide tension measurement.
D.2500	Cutaneous oxygen (PcO2) monitor	2	A cutaneous oxygen (PcO2) monitor is a noninvasive, heated sensor (e.g., a Clark-type polargraphic electrode) placed on the patient's skin that is intended to monitor relative changes in the cutaneous oxygen tension.
D.2550	Pneumotachometer	2	A pneumotachometer is a device intended for medical purposes that is used to determine gas flow by measuring the pressure differential across a known resistance. The device may use a set of capillaries or a metal screen for the resistive element.
D.2600	Airway pressure monitor	2	An airway pressure monitor is a device used to measure the pressure in a patient's upper airway. The device may include a pressure gauge and an alarm.
D.2610	Gas pressure gauge	1	A gas pressure gauge (e.g., bourdon tube pressure gauge) is a device intended for medical purposes that is used to measure gas pressure in a medical gas delivery system.
D.2700	Pressure regulator	1	A pressure regulator is a device, often called a pressure-reducing valve, that is intended for medical purposes and that is used to convert a medical gas pressure from a high variable pressure to a lower, more constant working pressure. This device includes mechanical oxygen regulators.
D.2775	Electrical peripheral nerve stimulator	2	An electrical peripheral nerve stimulator (neuromuscular blockade monitor) is a device used to apply an electrical current to a patient to test the level of pharmacological effect of anesthetic drugs and gases.
D.2875	Differential pressure transducer	1	A differential pressure transducer is a two-chambered device intended for medical purposes that is often used during pulmonary function testing. It generates an electrical signal for subsequent display or processing that is proportional to the difference in gas pressures in the two chambers.
D.2885	Gas flow transducer	1	A gas flow transducer is a device intended for medical purposes that is used to convert gas flow rate into an electrical signal for subsequent display or processing.
D.2900	Gas pressure transducer	1	A gas pressure transducer is a device intended for medical purposes that is used to convert gas pressure into an electrical signal for subsequent display or processing.
D.5090	Emergency airway needle	2	An emergency airway needle is a device intended to puncture a patient's cricothyroid membrane to provide an emergency airway during upper airway obstruction.
D.5100	Nasopharyngeal airway	1	A nasopharyngeal airway is a device used to aid breathing by means of a tube inserted into a patient's pharynx through the nose to provide a patent airway.
D.5105	External negative pressure airway aid	2	An external negative pressure airway aid is a prescription device that applies negative pressure to a patient's neck to aid in providing a patent airway during procedures requiring anesthesia.

D.5110	Oropharyngeal airway	1	An oropharyngeal airway is a device inserted into a patient's pharynx through the mouth to provide a patent airway.
D.5115	Device to relieve acute upper airway obstruction	2	The device is a raised, rounded pad that, in the event of choking on a foreign body, can be applied to the abdomen and pushed upward to generate expulsion pressure to remove the obstruction to relieve acute upper airway obstruction.
D.5120	Anesthesia conduction catheter	2	An anesthesia conduction catheter is a flexible tubular device used to inject local anesthetics into a patient and to provide continuous regional anesthesia.
D.5130	Anesthesia conduction filter	2	An anesthesia conduction filter is a microporous filter used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.
D.5140	Anesthesia conduction kit	2	An anesthesia conduction kit is a device used to administer to a patient conduction, regional, or local anesthesia. The device may contain syringes, needles, and drugs.
D.5150	Anesthesia conduction needle	2	An anesthesia conduction needle is a device used to inject local anesthetics into a patient to provide regional anesthesia.
D.5160	Gas machine for anesthesia or analgesia	2	(a)Gas machine for anesthesia. A gas machine for anesthesia is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation. The device may include a gas flowmeter, vaporizer, ventilator, breathing circuit with bag, and emergency air supply.(b)Gas machine for analgesia. A gas machine for analgesia is a device used to administer to a patient an analgesic agent, such as a nitrous oxide-oxygen mixture (maximum concentration of 70 percent nitrous oxide).
D.5165	Nitric oxide administration apparatus	2	The nitric oxide administration apparatus is a device used to add nitric oxide to gases that are to be breathed by a patient. The nitric oxide administration apparatus is to be used in conjunction with a ventilator or other breathing gas administration system.
D.5170	Laryngotracheal topical anesthesia applicator	2	A laryngotracheal topical anesthesia applicator is a device used to apply topical anesthetics to a patient's laryngotracheal area.
D.5180	Rocking bed	2	A rocking bed is a device intended for temporary use to help patient ventilation (breathing) by repeatedly tilting the patient, thereby using the weight of the abdominal contents to move the diaphragm.
D.5220	Blow bottle	1	A blow bottle is a device that is intended for medical purposes to induce a forced expiration from a patient. The patient blows into the device to move a column of water from one bottle to another.
D.5240	Anesthesia breathing circuit	1	An anesthesia breathing circuit is a device that is intended to administer medical gases to a patient during anesthesia. It provides both an inhalation and exhalation route and may include a connector, adaptor, and Y-piece.

D.5250	Breathing circuit circulator	2	A breathing circuit circulator is a turbine device that is attached to a closed breathing circuit and that is intended to circulate anesthetic gases continuously by maintaining the unidirectional valves in an open position and reducing mechanical dead space and resistance in the breathing circuit.
D.5260	Breathing circuit bacterial filter	2	A breathing circuit bacterial filter is a device that is intended to remove microbiological and particulate matter from the gases in the breathing circuit.
D.5270	Breathing system heater	2	A breathing system heater is a device that is intended to warm breathing gases before they enter a patient's airway. The device may include a temperature controller.
D.5273	Positive airway pressure delivery system	2	A positive airway pressure delivery system is a prescription noninvasive ventilatory device that delivers expiratory positive airway pressure for patients suffering from obstructive sleep apnea. The system also provides positive airway pressure during incipient apnea. The system may include a dedicated flow generator and a patient interface.
D.5280	Breathing tube support	1	A breathing tube support is a device that is intended to support and anchor a patient's breathing tube(s).
D.5300	Carbon dioxide absorbent	1	A carbon dioxide absorbent is a device intended for medical purposes that consists of an absorbent material (e.g., soda lime) that is intended to remove carbon dioxide from the gases in the breathing circuit.
D.5310	Carbon dioxide absorber	1	A carbon dioxide absorber is a device that is intended for medical purposes and that is used in a breathing circuit as a container for carbon dioxide absorbent. It may include a canister and water drain.
D.5320	Reservoir bag	1	A reservoir bag is a device, usually made of conductive rubber, intended for use in a breathing circuit as a reservoir for breathing gas and to assist, control, or monitor a patient's ventilation.
D.5330	Breathing gas mixer	2	A breathing gas mixer is a device intended for use in conjunction with a respiratory support apparatus to control the mixing of gases that are to be breathed by a patient.
D.5340	Nasal oxygen cannula	1	A nasal oxygen cannula is a two-pronged device used to administer oxygen to a patient through both nostrils.
D.5350	Nasal oxygen catheter	1	A nasal oxygen catheter is a device intended to be inserted through a patient's nostril to administer oxygen.
D.5375	Heat and moisture condenser (artificial nose)	1	A heat and moisture condenser (artificial nose) is a device intended to be positioned over a tracheotomy (a surgically created opening in the throat) or tracheal tube (a tube inserted into the trachea) to warm and humidify gases breathed in by a patient.
D.5400	Electroanesthesia apparatus	3	An electroanesthesia apparatus is a device used for the induction and maintenance of anesthesia during surgical procedures by means of an alternating or pulsed electric current that is passed through electrodes fixed to a patient's head.
D.5430	Gas-scavenging apparatus	2	A gas-scavenging apparatus is a device intended to collect excess anesthetic, analgesic, or trace gases or vapors from a patient's breathing system, ventilator, or extracorporeal pump-oxygenator, and to conduct these gases out of the area by means of an exhaust system.

D.5440	Portable oxygen generator	2	A portable oxygen generator is a device that is intended to release oxygen for respiratory therapy by means of either a chemical reaction or physical means (e.g., a molecular sieve).
D.5450	Respiratory gas humidifier	2	A respiratory gas humidifier is a device that is intended to add moisture to, and sometimes to warm, the breathing gases for administration to a patient. Cascade, gas, heated, and prefilled humidifiers are included in this generic type of device.
D.5454	High flow humidified oxygen delivery device	2	A high flow humidified oxygen delivery device is a prescription device that delivers high flow oxygen with humidification for patients who are suffering from respiratory distress and/or hypoxemia.
D.5460	Therapeutic humidifier for home use	1	A therapeutic humidifier for home use is a device that adds water vapor to breathing gases and that is intended for respiratory therapy or other medical purposes. The vapor produced by the device pervades the area surrounding the patient, who breathes the vapor during normal respiration.
D.5470	Hyperbaric chamber	2	A hyperbaric chamber is a device that is intended to increase the environmental oxygen pressure to promote the movement of oxygen from the environment to a patient's tissue by means of pressurization that is greater than atmospheric pressure. This device does not include topical oxygen chambers for extremities (I.5650).
D.5530	Flexible laryngoscope	1	A flexible laryngoscope is a fiberoptic device used to examine and visualize a patient's upper airway and aid placement of a tracheal tube.
D.5540	Rigid laryngoscope	1	A rigid laryngoscope is a device used to examine and visualize a patient's upper airway and aid placement of a tracheal tube.
D.5550	Anesthetic gas mask	1	An anesthetic gas mask is a device, usually made of conductive rubber, that is positioned over a patient's nose or mouth to direct anesthetic gases to the upper airway.
D.5560	Gas mask head strap	1	A gas mask head strap is a device used to hold an anesthetic gas mask in position on a patient's face.
D.5570	Nonrebreathing mask	1	A nonrebreathing mask is a device fitting over a patient's face to administer oxygen. It utilizes one-way valves to prevent the patient from rebreathing previously exhaled gases.
D.5580	Oxygen mask	1	An oxygen mask is a device placed over a patient's nose, mouth, or tracheostomy to administer oxygen or aerosols.
D.5590	Scavenging mask	1	A scavenging mask is a device positioned over a patient's nose to deliver anesthetic or analgesic gases to the upper airway and to remove excess and exhaled gas. It is usually used during dentistry.
D.5600	Venturi mask	1	A venturi mask is a device containing an air-oxygen mixing mechanism that dilutes 100 percent oxygen to a predetermined concentration and delivers the mixed gases to a patient.
D.5610	Membrane lung for long-term pulmonary support	3	A membrane lung for long-term pulmonary support is a device used to provide to a patient extracorporeal blood oxygenation for longer than 24 hours.

D.5620	Breathing mouthpiece	1	A breathing mouthpiece is a rigid device that is inserted into a patient's mouth and that connects with diagnostic or therapeutic respiratory devices.
D.5630	Nebulizer	2	A nebulizer is a device intended to spray liquids in aerosol form into gases that are delivered to lower respiratory tract of the patient. This device may contain a baffle to generate homogenious downsized aerosol. Heated, ultrasonic, gas, venturi, and refillable nebulizers are included in this generic type of device.
D.5640	Medicinal nonventilatory nebulizer (atomizer)	1	A medicinal nonventilatory nebulizer (atomizer) is a device that is intended to spray liquid medication in aerosol form that are delivered to upper respiratory tract of the patient.
D.5650	Esophageal obturator	2	An esophageal obturator is a device inserted through a patient's mouth to aid ventilation of the patient during emergency resuscitation by occluding (blocking) the esophagus, thereby permitting positive pressure ventilation through the trachea. The device consists of a closed-end semirigid esophageal tube that is attached to a face mask.
D.5665	Powered percussor	2	A powered percussor is a device that is intended to transmit vibration through a patient's chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage and that may be powered by electricity or compressed gas.
D.5675	Rebreathing device	1	A rebreathing device is a device that enables a patient to rebreathe exhaled gases. It may be used in conjunction with pulmonary function testing or for increasing minute ventilation.
D.5690	Incentive spirometer	2	An incentive spirometer is a device that indicates a patient's breathing volume or flow and that provides an incentive to the patient to improve his or her ventilation.
D.5700	Nonpowered oxygen tent	1	A nonpowered oxygen tent is a device that encloses a patient's head and upper body to contain oxygen delivered to the patient for breathing. This generic type of device includes infant oxygen hoods.
D.5710	Electrically powered oxygen tent	2	An electrically powered oxygen tent is a device that encloses a patient's head and, by means of an electrically powered unit, administers breathing oxygen and controls the temperature and humidity of the breathing gases. This generic type device includes the pediatric aerosol tent.
D.5720	Bronchial tube	2	A bronchial tube is a device used to differentially intubate a patient's bronchus (one of the two main branches of the trachea leading directly to the lung) in order to isolate a portion of lung distal to the tube.
D.5730	Tracheal tube	2	A tracheal tube is a device inserted into a patient's trachea via the nose or mouth and used to maintain an open airway.
D.5740	Tracheal/bronchial differential ventilation tube	2	A tracheal/bronchial differential ventilation tube is a device used to isolate the left or the right lung of a patient for anesthesia or pulmonary function testing.
D.5750	Inflatable tracheal tube cuff	2	An inflatable tracheal tube cuff is a device used to provide an airtight seal between a tracheal tube and a patient's trachea.

D.5770	Tracheal tube fixation device	1	A tracheal tube fixation device is a device used to hold a tracheal tube in place, usually by means of straps or pinch rings.
D.5780	Tube introduction forceps	1	Tube introduction forceps (e.g., Magill forceps) are a right-angled device used to grasp a tracheal tube and place it in a patient's trachea.
D.5790	Tracheal tube stylet	1	A tracheal tube stylet is a device used temporarily to make rigid a flexible tracheal tube to aid its insertion into a patient.
D.5800	Tracheostomy tube and tube cuff	2	A tracheostomy tube and tube cuff is a device intended to be placed into a surgical opening of the trachea to facilitate ventilation to the lungs. The cuff may be a separate or integral part of the tracheostomy tube and is, when inflated, intended to establish a seal between the tracheal wall and the tracheostomy tube. The cuff is used to prevent the patient's aspiration of substances, such as blood or vomit, or to provide a means for positive-pressure ventilation of the patient. This device is made of either stainless steel or plastic.
D.5810	Airway connector	1	An airway connector is a device intended to connect a breathing gas source to a tracheal tube, tracheostomy tube, or mask.
D.5830	Autotransfusion apparatus	2	An autotransfusion apparatus is a device used to collect and reinfuse the blood lost by a patient due to surgery or trauma.
D.5860	Pressure tubing and accessories	1	Pressure tubing and accessories are flexible or rigid devices intended to deliver pressurized medical gases.
D.5870	Nonrebreathing valve	2	A nonrebreathing valve is a one-way valve that directs breathing gas flow to the patient and vents exhaled gases into the atmosphere.
D.5880	Anesthetic vaporizer	2	An anesthetic vaporizer is a device used to vaporize liquid anesthetic and deliver a controlled amount of the vapor to the patient.
D.5895	Continuous ventilator and accessories	2	A continuous ventilator (respirator) and accessories is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device. Face masks intended to be used with continuous ventilators are included in this classification.
D.5905	Noncontinuous ventilator (IPPB) and accessories	2	A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) and accessories are the device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing. This device is intended to use with accessories such as masks of noncontinuous ventilator.
D.5915	Manual emergency ventilator	2	A manual emergency ventilator is a device, usually incorporating a bag and valve, intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.

D.5925	Powered emergency ventilator	2	A powered emergency ventilator is a demand valve or inhalator intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.
D.5935	External negative pressure ventilator	2	An external negative pressure ventilator (e.g., iron lung, cuirass) is a device chamber that is intended to support a patient's ventilation by alternately applying and releasing external negative pressure over the diaphragm and upper trunk of the patient.
D.5955	Intermittent mandatory ventilation attachment	2	An intermittent mandatory ventilation (IMV) attachment is a device attached to a mechanical ventilator that allows spontaneous breathing by a patient while providing mechanical ventilation at a preset rate.
D.5965	Positive end expiratory pressure breathing attachment	2	A positive end expiratory pressure (PEEP) breathing attachment is a device attached to a ventilator that is used to elevate pressure in a patient's lungs above atmospheric pressure at the end of exhalation.
D.5975	Ventilator tubing	1	Ventilator tubing is a device intended for use as a conduit for gases between a ventilator and a patient during ventilation of the patient.
D.5995	Tee drain (water trap)	1	A tee drain (water trap) is a device intended to trap and drain water that collects in ventilator tubing during respiratory therapy, thereby preventing an increase in breathing resistance.
D.6250	Portable air compressor	2	A portable air compressor is a device intended to provide compressed air for medical purposes, e.g., to drive ventilators and other respiratory devices.
D.6810	Tracheobronchial suction catheter	1	A tracheobronchial suction catheter is a device used to aspirate liquids or semisolids from a patient's upper airway.
D.6885	Medical gas yoke assembly	1	A medical gas yoke assembly is a device intended to connect medical gas cylinders to regulators or needle valves to supply gases for anesthesia or respiratory therapy. The device may include a particulate filter.
D.9999	Others(Anesthesiology Devices)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.
E.0001	Cardiovascular stent	3	Cardiovascular stent is a tube device which is intended to permanent implanted in human vessel or artificial vessel. This device provides mechanical support to maintain vessel patency. Depending on the placement mechanism, these devices include balloon-expanding stents and self-expanding stents. Classification:(1) Class 2 devices intended to be placed in peripheral arteries. For example Renal stents, Iliac stents, Superficial femoral Artery stents；(2) Class 3 devices intended to be placed other than peripheral arteries. For example, Coronary stents, and Carotid stents.
E.0002	Cardiovascular excimer laser system	3	Cardiovascular excimer laser system is intended for the photoablation or debulking of vascular lesion material (blockages, total occlusions). This device is used with an atherectomy catheter and typically consists of an electrical unit with a display, controls ,and/or foot-switch and excimer laser generator.
E.0004	Heart preservation/transport system	2	A heart preservation/transport system is a device designed to maintain donated heart in an almost physiological state until the heart transplant to the recipient.

E.0005	Percutaneous transluminal coronary angioplasty (PTCA) catheter	2,3	(a) Standard PTCA catheter (1) Identification: A PTCA catheter is a device that operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end. A PTCA balloon catheter has a single or double lumen shaft. The catheter features a balloon of appropriate compliance for the clinical application, constructed from a polymer. The balloon is designed to uniformly expand to a specified diameter and length at a specific pressure as labeled, with well characterized rates of inflation and deflation and a defined burst pressure. The device generally features a type of radiographic marker to facilitate fluoroscopic visualization of the balloon during use. A PTCA catheter is intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. A PTCA catheter may also be intended for the treatment of acute myocardial infarction; treatment of in-stent restenosis (ISR) and/or post-deployment stent expansion. (2) Classification: Class 2. (b) Cutting/scoring PTCA catheter (1) Identification: A cutting/scoring PTCA catheter is a balloon-tipped catheter with cutting/scoring elements attached, which is used in those circumstances where a high pressure balloon resistant lesion is encountered. A cutting/scoring PTCA catheter is intended for the treatment of hemodynamically significant coronary artery stenosis for the purpose of improving myocardial perfusion. A cutting/scoring PTCA catheter may also be indicated for use in complex type C lesions or for the treatment of in-stent restenosis. (2) Classification: Class 3.
E.0006	Endovascular graft system	3	An endovascular graft system is a device partially or completely placed in the human or artificial blood vessels. This device is intended for the revision of arteriovenous access circuits to maintain or re-establish vascular access. This device is deployed through the vessel circuit. Endovascular graft systems for aortic aneurysm treatment and arteriovenous (AV) dialysis access circuit stenosis treatment are included in this classification.
E.0008	Percutaneous cardiac ablation system	2,3	A percutaneous cardiac ablation system is intended for cardiac ablation surgery. This system contains percutaneous cardiac ablation catheter, RF ablation generator, cryoablation system, cooling catheter and cooling pump. Catheter remote control system is not included in this classification. Classification: (1) Class 2: RF ablation generator, cryoablation system, cooling catheter and cooling pump. (2) Class 3: percutaneous cardiac ablation catheter.
E.1025	Arrhythmia detector and alarm	3	The arrhythmia detector and alarm device monitors an electrocardiogram and is designed to produce a visible or audible signal or alarm when atrial or ventricular arrhythmia, such as premature contraction or ventricular fibrillation, occurs.
E.1100	Blood pressure alarm	2	A blood pressure alarm is a device that accepts the signal from a blood pressure transducer amplifier, processes the signal, and emits an alarm when the blood pressure falls outside a pre-set upper or lower limit.
E.1110	Blood pressure computer	2	A blood pressure computer is a device that accepts the electrical signal from a blood pressure transducer amplifier and indicates the systolic, diastolic, or mean pressure based on the input signal.

E.1120	Blood pressure cuff	2	A blood pressure cuff is a device that has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with another device to determine a subject's blood pressure.
E.1130	Noninvasive blood pressure measurement system	2	A noninvasive blood pressure measurement system is a device that provides a signal from which systolic, diastolic, mean, or any combination of the three pressures can be derived through the use of tranducers placed on the surface of the body.
E.1140	Venous blood pressure manometer	2	A venous blood pressure manometer is a device attached to a venous catheter to indicate manometrically the central or peripheral venous pressure.
E.1200	Diagnostic intravascular catheter	2	An intravascular diagnostic catheter is a device used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels. Included in this generic device are right-heart catheters, left-heart catheters, and angiographic catheters, among others.
E.1210	Continuous flush catheter	2	A continuous flush catheter is an attachment to a catheter-transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage, and waveform damping.
E.1220	Electrode recording catheter or electrode recording probe	2	An electrode recording catheter or an electrode recording probe is a device used to detect an intracardiac electrocardiogram, or to detect cardiac output or left-to-right heart shunts. The device may be unipolar or multipolar for electrocardiogram detection, or may be a platinum-tipped catheter which senses the presence of a special indicator for cardiac output or left-to-right heart shunt determinations.
E.1230	Fiberoptic oximeter catheter	2	A fiberoptic oximeter catheter is a device used to estimate the oxygen saturation of the blood. It consists of two fiberoptic bundles that conduct light at a desired wavelength through blood and detect the reflected and scattered light at the distal end of the catheter.
E.1240	Flow-directed catheter	2	A flow-directed catheter is a device that incorporates a gas-filled balloon to help direct the catheter to the desired position.
E.1250	Percutaneous catheter	2	A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire.
E.1251	Temporary catheter for embolic protection during transcatheter intracardiac procedures	2	This device is a single use percutaneous catheter system that has (a) blood filter(s) at the distal end. This device is indicated for use while performing transcatheter intracardiac procedures. The device is used to filter blood in a manner that may prevent embolic material (thrombus/debris) from the transcatheter intracardiac procedure from traveling towards the cerebral circulation.
E.1255	Balloon aortic valvuloplasty catheter	2	A balloon aortic valvuloplasty catheter is a catheter with a balloon at the distal end of the shaft, which is intended to treat stenosis in the aortic valve when the balloon is expanded.

E.1270	Intracavitary phonocatheter system	2	An intracavitary phonocatheter system is a system that includes a catheter with an acoustic transducer and the associated device that processes the signal from the transducer; this device records bioacoustic phenomena from a transducer placed within the heart, blood vessels, or body cavities.
E.1280	Steerable catheter	2	A steerable catheter is a catheter used for diagnostic and monitoring purposes whose movements are directed by a steering control unit.
E.1290	Steerable catheter control system	2	A steerable catheter control system is a device that is connected to the proximal end of a steerable guide wire that controls the motion of the steerable catheter.
E.1300	Catheter cannula	2	A catheter cannula is a hollow tube which is inserted into a vessel or cavity; this device provides a rigid or semirigid structure which can be connected to a tube or connector.
E.1310	Vessel dilator for percutaneous catheterization	2	A vessel dilator for percutaneous catheterization is a device which is placed over the guide wire to enlarge the opening in the vessel, and which is then removed before sliding the catheter over the guide wire.
E.1330	Catheter guide wire	2	A catheter guide wire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.
E.1340	Catheter introducer	2	A catheter introducer is a sheath used to facilitate placing a catheter through the skin into a vein or artery.
E.1350	Catheter balloon repair kit	3	A catheter balloon repair kit is a device used to repair or replace the balloon of a balloon catheter. The kit contains the materials, such as glue and balloons, necessary to effect the repair or replacement.
E.1360	Trace microsphere	3	A trace microsphere is a radioactively tagged nonbiodegradable particle that is intended to be injected into an artery or vein and trapped in the capillary bed for the purpose of studying blood flow within or to an organ.
E.1370	Catheter tip occluder	2	A catheter tip occluder is a device that is inserted into certain catheters to prevent flow through one or more orifices.
E.1380	Catheter stylet	2	A catheter stylet is a wire that is run through a catheter or cannula to render it stiff.
E.1390	Trocar	2	A trocar is a sharp-pointed instrument used with a cannula for piercing a vessel or chamber to facilitate insertion of the cannula.
E.1415	Coronary vascular physiologic simulation software device	2	A coronary vascular physiologic simulation software device is a prescription device that provides simulated functional assessment of blood flow in the coronary vascular system using data extracted from medical device imaging to solve algorithms and yield simulated metrics of physiologic information (e.g., blood flow, coronary flow reserve, fractional flow reserve, myocardial perfusion). A coronary vascular physiologic simulation software device is intended to generate results for use and review by a qualified clinician.
E.1425	Programmable diagnostic computer	2	A programmable diagnostic computer is a device that can be programmed to compute various physiologic or blood flow parameters based on the output from one or more electrodes, transducers, or measuring devices; this device includes any associated commercially supplied programs.

E.1435	Single-function preprogrammed diagnostic computer	2	A single-function, preprogrammed diagnostic computer is a hard-wired computer that calculates a specific physiological or blood-flow parameter based on information obtained from one or more electrodes, transducers, or measuring devices.
E.1450	Densitometer	2	A densitometer is a device used to measure the transmission of light through an indicator in a sample of blood.
E.1650	Angiographic injector and syringe	2	An angiographic injector and syringe is a device that consists of a syringe and a high-pressure injector which are used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography.
E.1660	Indicator injector	2	An indicator injector is an electrically or gas-powered device designed to inject accurately an indicator solution into the blood stream. This device may be used in conjuction with a densitometer or thermodilution device to determine cardiac output.
E.1670	Syringe actuator for an injector	2	A syringe actuator for an injector is an electrical device that controls the timing of an injection by an angiographic or indicator injector and synchronizes the injection with the electrocardiograph signal.
E.1750	External programmable pacemaker pulse generator	2	An external programmable pacemaker pulse generators is a device that can be programmed to produce one or more pulses at preselected intervals; this device is used in electrophysiological studies.
E.1800	Withdrawal-infusion pump	2	A withdrawal-infusion pump is a device designed to inject accurately drugs into the bloodstream and to withdraw blood samples for use in determining cardiac output.
E.1875	Stethoscope	1,2	(a)Manual stethoscope --(1)Identification: A manual stethoscope is a mechanical device used to project the sounds associated with the heart, arteries, and veins and other internal organs.(2)Classification: Class 1. (b)Electronic stethoscope --(1)Identification: An electronic stethoscope is an electrically amplified device used to project the sounds associated with the heart, arteries, and veins and other internal organs. (2)Classification: Class 2.
E.1915	Thermodilution probe	2	A thermodilution probe is a device that monitors cardiac output by use of thermodilution techniques; this device is commonly attached to a catheter that may have one or more probes.
E.2050	Biopotential amplifier and signal conditioner	2	A biopotential amplifier and signal conditioner is a device used to amplify or condition an electrical signal of biologic origin.
E.2060	Transducer signal amplifier and signal conditioner	2	A transducer signal amplifier and conditioner is a device used to provide the excitation energy for the transducer and to amplify or condition the signal emitted by the transducer.
E.2100	Cardiovascular blood flowmeter	2	A cardiovascular blood flowmeter is a device that is connected to a flow transducer that energizes the transducer and processes and displays the blood flow signal.

E.2120	Extravascular blood flow probe	2	An extravascular blood flow probe is an extravascular ultrasonic or electromagnetic probe used in conjunction with a blood flowmeter to measure blood flow in a chamber or vessel.
E.2300	Cardiac monitor (including cardiotachometer and rate alarm)	2	A cardiac monitor (including cardiotachometer and rate alarm) is a device used to measure the heart rate from an analog signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor. This device may sound an alarm when the heart rate falls outside preset upper and lower limits.
E.2310	Apex cardiograph (vibrocardiograph)	2	An apex cardiograph (vibrocardiograph) is a device used to amplify or condition the signal from an apex cardiographic transducer and to produce a visual display of the motion of the heart; this device also provides any excitation energy required by the transducer.
E.2320	Ballistocardiograph	2	A ballistocardiograph is a device, including a supporting structure on which the patient is placed, that moves in response to blood ejection from the heart. The device often provides a visual display.
E.2330	Echocardiograph	2	An echocardiograph is a device that uses ultrasonic energy to create images of cardiovascular structures. It includes phased arrays and two-dimensional scanners.
E.2340	Electrocardiograph	2	An electrocardiograph is a device used to process the electrical signal transmitted through two or more electrocardiograph electrodes and to produce a visual display of the electrical signal produced by the heart.
E.2350	Electrocardiograph lead switching adaptor	2	An electrocardiograph lead switching adaptor is a passive switching device to which electrocardiograph limb and chest leads may be attached. This device is used to connect various combinations of limb and chest leads to the output terminals in order to create standard lead combinations such as leads I, II, and III.
E.2360	Electrocardiograph electrode	2	An electrocardiograph electrode is the electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram.
E.2390	Phonocardiograph	1	A phonocardiograph is a device used to amplify or condition the signal from a heart sound transducer. This device furnishes the excitation energy for the transducer and provides a visual or audible display of the heart sounds.
E.2400	Vectrocardiograph	2	A vectorcardiograph is a device used to process the electrical signal transmitted through electrocardiograph electrodes and to produce a visual display of the magnitude and direction of the electrical signal produced by the heart.
E.2450	Medical cathode-ray tube display	2	A medical cathode-ray tube display is a device designed primarily to display selected biological signals. This device often incorporates special display features unique to a specific biological signal.
E.2675	Oscillometer	2	An oscillometer is a device used to measure physiological oscillations of any kind, e.g., changes in the volume of arteries.

E.2700	Oximeter	2	An oximeter is a device used to transmit radiation at a known wavelength(s) through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation. It may be used alone or in conjunction with a fiberoptic oximeter catheter.
E.2710	Ear oximeter	2	An ear oximeter is an extravascular device used to transmit light at a known wavelength(s) through blood in the ear. The amount of reflected or scattered light as indicated by this device is used to measure the blood oxygen saturation.
E.2750	Impedance phlebograph	2	An impedance phlebograph is a device used to provide a visual display of the venous pulse or drainage by measuring electrical impedance changes in a region of the body.
E.2770	Impedance plethysmograph)	2	An impedance plethysmograph is a device used to estimate peripheral blood flow by measuring electrical impedance changes in a region of the body such as the arms and legs.
E.2780	Hydraulic,pneumatic,or photoelectric plethysmographs	2	A hydraulic, pneumatic, or photoelectric plethysmograph is a device used to estimate blood flow in a region of the body using hydraulic, pneumatic, or photoelectric measurement techniques.
E.2800	Medical magnetic tape recorder	2	A medical magnetic tape recorder is a device used to record and play back signals from, for example, physiological amplifiers, signal conditioners, or computers.
E.2840	Apex cardiograph transducer	2	An apex cardiographic transducer is a device used to detect motion of the heart (acceleration, velocity, or displacement) by changes in the mechanical or electrical properties of the device.
E.2850	Extravascular blood pressure transducer	2	An extravascular blood pressure transducer is a device used to measure blood pressure by changes in the mechanical or electrical properties of the device. The proximal end of the transducer is connected to a pressure monitor that produces an analog or digital electrical signal related to the electrical or mechanical changes produced in the transducer.
E.2855	Implantable Intra-aneurysm Pressure Measurement System	2	Implantable intra-aneurysm pressure measurement system is a device used to measure the intra-sac pressure in a vascular aneurysm. The device consists of a pressure transducer that is implanted into the aneurysm and a monitor that reads the pressure from the transducer.
E.2860	Heart sound transducer	2	A heart sound transducer is an external transducer that exhibits a change in mechanical or electrical properties in relation to sounds produced by the heart. This device may be used in conjunction with a phonocardiograph to record heart sounds.
E.2870	Catheter tip pressure transducer	2	A catheter tip pressure transducer is a device incorporated into the distal end of a catheter. When placed in the bloodstream, its mechanical or electrical properties change in relation to changes in blood pressure. These changes are transmitted to accessory equipment for processing.

E.2880	Ultrasonic transducer	2	An ultrasonic transducer is a device applied to the skin to transmit and receive ultrasonic energy that is used in conjunction with an echocardiograph to provide imaging of cardiovascular structures. This device includes phased arrays and two-dimensional scanning transducers.
E.2890	Vessel occlusion transducer	2	A vessel occlusion transducer is a device used to provide an electrical signal corresponding to sounds produced in a partially occluded vessel. This device includes motion, sound, and ultrasonic transducers.
E.2900	Patient transducer and electrode cable (including connector)	2	A patient transducer and electrode cable (including connector) is an electrical conductor used to transmit signals from, or power or excitation signals to, patient-connected electrodes or transducers.
E.2910	Radiofrequency physiological signal transmitter and receiver	2	A radiofrequency physiological signal transmitter and receiver is a device used to condition a physiological signal so that it can be transmitted via radiofrequency from one location to another, e.g., a central monitoring station. The received signal is reconditioned by the device into its original format so that it can be displayed.
E.2920	Telephone electrocardiograph transmitter and receiver	2	A telephone electrocardiograph transmitter and receiver is a device used to condition an electrocardiograph signal so that it can be transmitted via a telephone line to another location. This device also includes a receiver that reconditions the received signal into its original format so that it can be displayed. The device includes devices used to transmit and receive pacemaker signals.
E.3250	Vascular clip	2	A vascular clip is an implanted extravascular device designed to occlude, by compression, blood flow in small blood vessels other than intracranial vessels.
E.3260	Vena cava clip	2	A vena cava clip is an implanted extravascular device designed to occlude partially the vena cava for the purpose of inhibiting the flow of thromboemboli through that vessel.
E.3300	Arterial embolization device	3	A vascular embolization device is an intravascular implant intended to control hemorrhaging due to aneurysms, certain types of tumors (e.g., nephroma, hepatoma, uterine fibroids), and arteriovenous malformations. This does not include cyanoacrylates and other embolic agents, which act by polymerization or precipitation. Embolization devices used in neurovascular applications are also not included in this classification, see K.5950 of this chapter.
E.3375	Cardiovascular intravascular filter	2	A cardiovascular intravascular filter is an implant that is placed in the inferior vena cava for the purpose of preventing pulmonary thromboemboli (blood clots generated in the lower limbs and broken loose into the blood stream) from flowing into the right side of the heart and the pulmonary circulation.
E.3450	Vascular graft prosthesis	2	A vascular graft prosthesis is an implanted device intended to repair, replace, or bypass sections of native or artificial vessels, excluding coronary or cerebral vasculature, and to provide vascular access. It is commonly constructed of materials such as polyethylene terephthalate and polytetrafluoroethylene, and it may be coated with a biological coating, such as albumin or collagen, or a synthetic coating, such as silicone. The graft structure itself is not made of materials of animal origin, including human umbilical cords.

E.3460	Endovascular suturing system	2	An endovascular suturing system is a medical device intended to provide fixation and sealing between an endovascular graft and the native artery. The system is comprised of the implant device and an endovascular delivery device used to implant the endovascular suture. Classification. Class II
E.3470	Intracardiac patch or pledget made of polypropylene,polyethylene terephthalate, or polytetrafluoroethylene	2	An intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene is a fabric device placed in the heart that is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures.
E.3535	Intra-aortic balloon and control system	2,3	(a) Identification: An intra-aortic balloon and control system is a device that consists of an inflatable balloon, which is placed in the aorta to improve cardiovascular functioning during certain life-threatening emergencies, and a control system for regulating the inflation and deflation of the balloon. The control system, which monitors and is synchronized with the electrocardiogram, provides a means for setting the inflation and deflation of the balloon with the cardiac cycle. (b) Classification: (1) Class 2: The device is indicated for acute coronary syndrome, cardiac and non-cardiac surgery, or complications of heart failure. (2) Class 3: The device is indicated for septic shock and pulsatile flow generation.
E.3545	Ventricular bypass (assist) device	3	A ventricular bypass (assist) device is a device that assists the left or right ventricle in maintaining circulatory blood flow. The device is either totally or partially implanted in the body.
E.3600	External pacemaker pulse generator	3	An external pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device, which is used outside the body, is used as a temporary substitute for the heart's intrinsic pacing sytem until a permanent pacemaker can be implanted, or to control irregular heartbeats in patients following cardiac surgery or a myocardial infarction. The device may have adjustments for impulse strength, duration, R-wave sensitivity, and other pacing variables.
E.3610	Implantable pacemaker pulse generator	3	An implantable pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device is used as a substitute for the heart's intrinsic pacing system to correct both intermittent and continuous cardiac rhythm disorders. This device includes triggered, inhibited, and asynchronous devices implanted in the human body.
E.3620	Pacemaker lead adaptor	2	A pacemaker lead adaptor is a device used to adapt a pacemaker lead so that it can be connected to a pacemaker pulse generator produced by a different manufacturer.
E.3630	Pacemaker generator function analyzer	2	A pacemaker generator function analyzer is a device that is connected to a pacemaker pulse generator to test any or all of the generator's parameters, including pulse duration, pulse amplitude, pulse rate, and sensing threshold.

E.3650	Pacemaker polymeric mesh bag	1	A pacemaker polymeric mesh bag is an implanted device used to hold a pacemaker pulse generator. The bag is designed to create a stable implant environment for the pulse generator.
E.3670	Pacemaker charger	1	A pacemaker charger is a device used transcutaneously to recharge the batteries of a rechargeable pacemaker.
E.3680	Cardiovascular permanent or temporary pacemaker electrode	2,3	(a)Temporary pacemaker electrode --(1)Identification: A temporary pacemaker electrode is a device consisting of flexible insulated electrical conductors with one end connected to anexternal pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator. (2)Classification: Class 2. (b)Permanent pacemaker electrode --(1)Identification: A permanent pacemaker electrode is a device consisting of flexible insulated electrical conductors with one end connected to an implantable pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator. (2)Classification: Class 3.
E.3690	Pacemaker test magnet	1	A pacemaker test magnet is a device used to test an inhibited or triggered type of pacemaker pulse generator and cause an inhibited or triggered generator to revert to asynchronous operation.
E.3700	Pacemaker programmers	3	A pacemaker programmer is a device used to change noninvasively one or more of the electrical operating characteristics of a pacemaker.
E.3710	Pacemaker repair or replacement material	3	A pacemaker repair or replacement material is an adhesive, a sealant, a screw, a crimp, or any other material used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker pulse generator.
E.3720	Pacemaker electrode function tester	2	A pacemaker electrode function tester is a device which is connected to an implanted pacemaker lead that supplies an accurately calibrated, variable pacing pulse for measuring the patient's pacing threshold and intracardiac R-wave potential.
E.3730	Pacemaker service tools	1	Pacemaker service tools are devices such as screwdrivers and Allen wrenches, used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker generator.
E.3800	Annuloplasty ring	2	An annuloplasty ring is a rigid or flexible ring implanted around the mitral or tricuspid heart valve for reconstructive treatment of valvular insufficiency.
E.3850	Carotid sinus nerve stimulator	3	A carotid sinus nerve stimulator is an implantable device used to decrease arterial pressure by stimulating Hering's nerve at the carotid sinus.
E.3925	Replacement heart valve	3	A replacement heart valve is a device intended to perform the function of any of the heart's natural valves. This device includes valves constructed of prosthetic materials, biologic valves (e.g., porcine valves), or valves constructed of a combination of prosthetic and biologic materials.

E.3935	Prosthetic heart valve holder	1	A prosthetic heart valve holder is a device used to hold a replacement heart valve while it is being sutured into place.
E.3945	Prosthetic heart valve sizer	1	A prosthetic heart valve sizer is a device used to measure the size of the natural valve opening to determine the size of the appropriate replacement heart valve.
E.4075	Endomyocardial biopsy device	2	An endomyocardial biopsy device is a device used in a catheterization procedure to remove samples of tissue from the inner wall of the heart.
E.4100	Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure	2	An extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary support (>6 hours) is a system of devices and accessories that provides assisted extracorporeal circulation and physiologic gas exchange of the patient's blood in patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. The main devices and accessories of the system include, but are not limited to, the console (hardware), software, and disposables, including, but not limited to, an oxygenator, blood pump, heat exchanger, cannulae, tubing, filters, and other accessories (e.g., monitors, detectors, sensors, connectors).
E.4200	Cardiopulmonary bypass accessory equipment	1,2	Cardiopulmonary bypass accessory equipment is a device that has no contact with blood and that is used in the cardiopulmonary bypass circuit to support, adjoin, or connect components, or to aid in the setup of the extracorporeal line, e.g., an oxygenator mounting bracket or system-priming equipment. Classification:(1)Class 1 devices do not involve an electrical connection to the patient.；(2)Class 2 devices involve an electrical connection to the patient.
E.4205	Cardiopulmonary bypass bubble detector	2	A cardiopulmonary bypass bubble detector is a device used to detect bubbles in the arterial return line of the cardiopulmonary bypass circuit.
E.4210	Cardiopulmonary bypass vascular catheter,cannula,or tubing	2	A cardiopulmonary bypass vascular catheter, cannula, or tubing is a device used in cardiopulmonary surgery to cannulate the vessels, perfuse the coronary arteries, and to interconnect the catheters and cannulas with an oxygenator. The device includes accessory bypass equipment.
E.4220	Cardiopulmonary bypass heart-lung machine console	2	A cardiopulmonary bypass heart-lung machine console is a device that consists of a control panel and the electrical power and control circuitry for a heart-lung machine. The console is designed to interface with the basic units used in a gas exchange system, including the pumps, oxygenator, and heat exchanger.
E.4230	Cardiopulmonary bypass defoamer	2	A cardiopulmonary bypass defoamer is a device used in conjunction with an oxygenator during cardiopulmonary bypass surgery to remove gas bubbles from the blood.
E.4240	Cardiopulmonary bypass heat exchanger	2	A cardiopulmonary bypass heat exchanger is a device, consisting of a heat exchange system used in extracorporeal circulation to warm or cool the blood or perfusion fluid flowing through the device.

E.4250	Cardiopulmonary bypass temperature controller	2	A cardiopulmonary bypass temperature controller is a device used to control the temperature of the fluid entering and leaving a heat exchanger.
E.4260	Cardiopulmonary bypass arterial line blood filter	2	A cardiopulmonary bypass arterial line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (blood clots or pieces of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. It is used in the arterial return line.
E.4270	Cardiopulmonary bypass cardiotomy suction line blood filter	2	A cardiopulmonary bypass cardiotomy suction line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (a blood clot or a piece of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. This device is intended for use in the cardiotomy suction line.
E.4280	Cardiopulmonary prebypass filter	2	A cardiopulmonary prebypass filter is a device used during priming of the oxygenator circuit to remove particulates or other debris from the circuit prior to initiating bypass. The device is not used to filter blood.
E.4290	Cardiopulmonary bypass adaptor,stopcock,manifold,or fitting	2	A cardiopulmonary bypass adaptor, stopcock, manifold, or fitting is a device used in cardiovascular diagnostic, surgical, and therapeutic applications to interconnect tubing, catheters, or other devices.
E.4300	Cardiopulmonary bypass gas control unit	2	A cardiopulmonary bypass gas control unit is a device used to control and measure the flow of gas into the oxygenator. The device is calibrated for a specific gas.
E.4310	Cardiopulmonary bypass coronary pressure gauge	2	A cardiopulmonary bypass coronary pressure gauge is a device used in cardiopulmonary bypass surgery to measure the pressure of the blood perfusing the coronary arteries.
E.4320	Cardiopulmonary bypass pulsatile flow generator	3	A cardiopulmonary bypass pulsatile flow generator is an electrically and pneumatically operated device used to create pulsatile blood flow. The device is placed in a cardiopulmonary bypass circuit downstream from the oxygenator.
E.4330	Cardiopulmonary bypass on-line blood gas monitor	2	A cardiopulmonary bypass on-line blood gas monitor is a device used in conjunction with a blood gas sensor to measure the level of gases in the blood.
E.4340	Cardiopulmonary bypass level sensing monitor and/or control	2	A cardiopulmonary bypass level sensing monitor and/or control is a device used to monitor and/or control the level of blood in the blood reservoir and to sound an alarm when the level falls below a predetermined value.
E.4350	Cardiopulmonary bypass oxygenator	2	A cardiopulmonary bypass oxygenator is a device used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during open-heart surgery.
E.4360	Nonroller-type cardiopulmonary bypass blood pump	3	A nonroller-type cardiopulmonary bypass blood pump is a device that uses a method other than revolving rollers to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.
E.4370	Roller-type cardiopulmonary bypass blood pump	2	A roller-type cardiopulmonary bypass blood pump is a device that uses a revolving roller mechanism to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.

E.4380	Cardiopulmonary bypass pump speed control	2	A cardiopulmonary bypass pump speed control is a device used that incorporates an electrical system or a mechanical system, or both, and is used to control the speed of blood pumps used in cardiopulmonary bypass surgery.
E.4390	Cardiopulmonary bypass pump tubing	2	A cardiopulmonary bypass pump tubing is polymeric tubing which is used in the blood pump head and which is cyclically compressed by the pump to cause the blood to flow through the cardiopulmonary bypass circuit.
E.4400	Cardiopulmonary bypass blood reservoir	2	A cardiopulmonary bypass blood reservoir is a device used in conjunction with short-term extracorporeal circulation devices to hold a reserve supply of blood in the bypass circulation.
E.4410	Cardiopulmonary bypass in-line blood gas sensor	2	A cardiopulmonary bypass in-line blood gas sensor is a transducer that measures the level of gases in the blood.
E.4420	Cardiopulmonary bypass cardiotomy return sucker	2	A cardiopulmonary bypass cardiotomy return sucker is a device that consists of tubing, a connector, and a probe or tip that is used to remove blood from the chest or heart during cardiopulmonary bypass surgery.
E.4430	Cardiopulmonary bypass intracardiac suction control	2	A cardiopulmonary bypass intracardiac suction control is a device which provides the vacuum and control for a cardiotomy return sucker.
E.4450	Vascular clamp	2	A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily.
E.4475	Surgical vessel dilator	2	A surgical vessel dilator is a device used to enlarge or calibrate a vessel.
E.4500	Cardiovascular surgical instruments	1	Cardiovascular surgical instruments are surgical instruments that have special features for use in cardiovascular surgery. These devices include, e.g., forceps, retractors, and scissors.
E.4510	Apical closure device	2	An apical closure device is a prescription device consisting of a delivery system and implant component that is used for soft tissue approximation of cardiac apical tissue during transcatheter valve replacement procedures.
E.4875	Intraluminal artery stripper	2	An intraluminal artery stripper is a device used to perform an endarterectomy (removal of plaque deposits from arteriscleroticarteries.)
E.4885	External vein stripper	2	An external vein stripper is an extravascular device used to remove a section of a vein.
E.5050	Patient care suction apparatus	2	A patient care suction apparatus is a device used with an intrathoracic catheter to withdraw fluid from the chest during the recovery period following surgery.
E.5150	Embolectomy catheter	2	An embolectomy catheter is a balloon-tipped catheter that is used to remove thromboemboli, i.e., blood clots which have migrated in blood vessels from one site in the vascular tree to another.
E.5175	Septostomy catheter	2	A septostomy catheter is a special balloon catheter that is used to create or enlarge the atrial septal defect found in the heart of certain infants.
E.5200	External cardiac compressor	3	An external cardiac compressor is an external device that is electrically, pneumatically, or manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest.

E.5210	CPR aid	1, 2	(a)A CPR aid without feedback is a device that performs a simple function such as proper hand placement and/or simple prompting for rate and/or timing of compressions/breathing for the professionally trained rescuer, but offers no feedback related to the quality of the CPR being provided. These devices are intended for use by persons professionally trained in CPR to assure proper use and the delivery of optimal CPR to the victim. Classification. Class I (b)A CPR Aid device with feedback is a device that provides real-time feedback to the rescuer regarding the quality of CPR being delivered to the victim, and provides either audio and/or visual information to encourage the rescuer to continue the consistent application of effective manual CPR in accordance with current accepted CPR guidelines (to include, but not be limited to, parameters such as compression rate, compression depth, ventilation, recoil, instruction for one or multiple rescuers, etc.). These devices may also perform a coaching function to aid rescuers in the sequence of steps necessary to perform effective CPR on a victim. Classification. Class II
E.5225	External counter-pulsating device	2,3	(a) Identification: An external counter-pulsating device is a noninvasive device used to assist the heart by applying positive or negative pressure to one or more of the body's limbs in synchrony with the heart cycle. (b) Classification: (1) Class 2: The device is for the treatment of chronic stable angina. (2) Class 3: Those that do not fit the description listed in Class 2.
E.5300	DC-defibrillator(including paddles)	2,3	(a)Low-energy DC-defibrillator --(1)Identification: A low-energy DC-defibrillator is a device that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart or to terminate other cardiac arrhythmias. This generic type of device includes low energy defibrillators with a maximum electrical output of less than 360 joules of energy that are used in pediatric defibrillation or in cardiac surgery. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body. (2)Classification: Class 2. (b)High-energy DC-defibrillator --(1)Identification: A high-energy DC-defibrillator is a device that delivers into a 50 ohm test load an electrical shock of greater than 360 joules of energy used for defibrillating the atria or ventricles of the heart or to terminate other cardiac arrhythmias. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body. (2)Classification: Class 3.

E.5310	Automated external defibrillator system	3	An automated external defibrillator (AED) system consists of an AED and those accessories necessary for the AED to detect and interpret an electrocardiogram and deliver an electrical shock (e.g., battery, pad electrode, adapter, and hardware key for pediatric use). An AED system analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.
E.5325	Defibrillator tester	2	A defibrillator tester is a device that is connected to the output of a defibrillator and is used to measure the energy delivered by the defibrillator into a standard resistive load. Some testers also provide waveform information.
E.5550	External transcutaneous cardiac pacemaker(noninvasive)	2	An external transcutaneous cardiac pacemaker (noninvasive) is a device used to supply a periodic electrical pulse intended to pace the heart. The pulse from the device is usually applied to the surface of the chest through electrodes such as defibrillator paddles.
E.5700	Steerable cardiac ablation catheter remote control system	2	A steerable cardiac ablation catheter remote control system is a prescription device that is external to the body and interacts with the manual handle of a steerable cardiac ablation catheter to remotely control the advancement, retraction, rotation, and deflection of a compatible, steerable ablation catheter used for the treatment of cardiac arrhythmias in the right side of the heart. The device allows reversion to manual control of the steerable cardiac ablation catheter without withdrawal of the catheter and interruption of the procedure.
E.5800	Compressible limb sleeve	2	A compressible limb sleeve is a device that is used to prevent pooling of blood in a limb by inflating periodically a sleeve around the limb.
E.5900	Thermal regulating system	2	A thermal regulating system is an external system consisting of a device that is placed in contact with the patient and a temperature controller for the device. The system is used to regulate patient temperature.
E.5910	Esophageal thermal regulation device	2	An esophageal thermal regulation device is a prescription device used to apply a specified temperature to the endoluminal surface of the esophagus via an external controller. This device may incorporate a mechanism for gastric decompression and suctioning. The device is used to regulate patient temperature.
E.5925	Automatic rotating tourniquet	2	An automatic rotating tourniquet is a device that prevents blood flow in one limb at a time, which temporarily reduces the total blood volume, thereby reducing the normal workload of the heart.
E.9999	Others(Cardiovascular Devices)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.
F.0001	Retraction cord	1,2	Retraction cord inserted in gums (gingiva) is used to extend the space between teeth and gums. Classification:(1) Retraction cord contains medicine is class 2. (2) Others are class 1.
F.0002	Orthodontic Planning Software	2	Orthodontic Planning Software is a software that is to be used for the diagnosis and treatment planning of orthodontic patients

F.1500	Gingival fluid measurer	1	A gingival fluid measurer is a gauge device intended to measure the amount of fluid in the gingival sulcus (depression between the tooth and gums) to determine if there is a gingivitis condition.
F.1720	Pulp tester	2	A pulp tester is an AC or battery powered device intended to evaluate the pulpal vitality of teeth by employing high frequency current transmitted by an electrode to stimulate the nerve tissue in the dental pulp.
F.1730	Electrode gel for pulp tester	1	An electrode gel for pulp testers is a device intended to be applied to the surface of a tooth before use of a pulp tester to aid conduction of electrical current.
F.1740	Caries detection device	2	The caries detection device is a device intended to show the existence of decay in a patient's tooth by use of electrical current.
F.1745	Laser fluorescence caries detection device	2	A laser fluorescence caries detection device is a laser, a fluorescence detector housed in a dental handpiece, and a control console that performs device calibration, as well as variable tone emitting and fluorescence measurement functions. The intended use of the device is to aid in the detection of tooth decay by measuring increased laser induced fluorescence.
F.1800	Extraoral source x-ray system	2	An extraoral source x-ray system is an AC-powered device that produces x-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The x-ray source (a tube) is located outside the mouth. This generic type of device may include patient and equipment supports and component parts.
F.1810	Intraoral source x-ray system	2	An intraoral source x-ray system is an electrically powered device that produces x-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The x-ray source (a tube) is located inside the mouth. This generic type of device may include patient and equipment supports and component parts.
F.1820	Dental x-ray exposure alignment device	1	A dental x-ray exposure alignment device is a device intended to position x-ray film and to align the examination site with the x-ray beam.
F.1830	Cephalometer	2	A cephalometer is a device used in dentistry during x-ray procedures. The device is intended to place and to hold a patient's head in a standard position during dental x-rays.
F.1840	Dental x-ray position indicating device	1	A dental x-ray position indicating device is a device, such as a collimator, cone, or aperture, that is used in dental radiographic examination. The device is intended to align the examination site with the x-ray beam and to restrict the dimensions of the dental x-ray field by limiting the size of the primary x-ray beam.
F.1850	Lead-lined position indicator	1	A lead-lined position indicator is a cone-shaped device lined with lead that is attached to a dental x-ray tube and intended to aid in positioning the tube, to prevent the misfocusing of the x-rays by absorbing divergent radiation, and to prevent leakage of radiation.

F.1870	Sulfide detection device	2	A sulfide detection device is a device consisting of an AC-powered control unit, probe handle, probe tips, cables, and accessories. This device is intended to be used in vivo, to manually measure periodontal pocket probing depths, detect the presence or absence of bleeding on probing, and detect the presence of sulfides in periodontal pockets, as an adjunct in the diagnosis of periodontal diseases in adult patients.
F.2050	Dental sonography device	1,2	(1)Dental sonography device for monitoring is an electrically powered device, intended to be used to monitor temporomandibular joint sounds. The device detects and records sounds made by the temporomandibular joint. Classification: Class 1. (2)Dental sonography device for interpretation and diagnosis is an electrically powered device, intended to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. The device detects, records, displays, and stores sounds made by the temporomandibular joint during jaw movement. The device interprets these sounds to generate meaningful output, either directly or by connection to a personal computer. The device may be part of a system of devices, contributing joint sound information to be considered with data from other diagnostic components. Classification: Class 2.
F.2060	Jaw tracking device	1,2	(a)Jaw tracking device for monitoring mandibular jaw positions relative to the maxilla --(1)Identification: A jaw tracking device for monitoring mandibular jaw positions relative to the maxilla is a nonpowered or electrically powered device that measures and records anatomical distances and angles in three dimensional space, to determine the relative position of the mandible with respect to the location and position of the maxilla, while at rest and during jaw movement.(2)Classification: Class 1. (b)Jaw tracking device for interpretation of mandibular jaw positions for the diagnosis --(1)Identification. A jaw tracking device for interpretation of mandibular jaw positions relative to the maxilla for the diagnosis of temporomandibular joint disorders and associated orofacial pain is a nonpowered or electrically powered device that measures and records anatomical distances and angles to determine the relative position of the mandible in three dimensional space, with respect to the location and position of the maxilla, while at rest and during jaw movement. The device records, displays, and stores information about jaw position. The device interprets jaw position to generate meaningful output, either directly or by connection to a personal computer. The device may be a part of a system of devices, contributing jaw position information to be considered with data from other diagnostic components. (2)Classification: Class 2.

F.3060	Gold based alloys and precious metal alloys for clinical use	2	A noble metal alloy is a device composed primarily of noble metals, such as gold, palladium, platinum, or silver, that is intended for use in the fabrication of cast or porcelain-fused-to-metal crown and bridge restorations.
F.3070	Dental amalgam, mercury, and amalgam alloy	2	Dental amalgam is a device that consists of a combination of elemental mercury, supplied as a liquid in bulk, sachet, or predosed capsule form, and amalgam alloy composed primarily of silver, tin, and copper, supplied as a powder in bulk, tablet, or predosed capsule form, for the direct filling of carious lesions or structural defects in teeth. This device also includes the individual component devices, mercury and amalgam alloy, when intended to be combined with each other to form dental amalgam.
F.3080	Mercury and alloy dispenser	1	A mercury and alloy dispenser is a device with a spring-activated valve intended to measure and dispense into a mixing capsule a predetermined amount of dental mercury in droplet form and a premeasured amount of alloy pellets.
F.3100	Dental amalgamator	1	A dental amalgamator is a device, usually AC-powered, intended to mix, by shaking, amalgam capsules containing mercury and dental alloy particles, such as silver, tin, zinc, and copper. The mixed dental amalgam material is intended for filling dental caries.
F.3110	Dental amalgam capsule	1	A dental amalgam capsule is a container device in which silver alloy is intended to be mixed with mercury to form dental amalgam.
F.3130	Preformed anchor	1	A preformed anchor is a device made of austenitic alloys or alloys containing 75 percent or greater gold or metals of the platinum group intended to be incorporated into a dental appliance, such as a denture, to help stabilize the appliance in the patient's mouth.
F.3140	Resin applicator	1	A resin applicator is a brushlike device intended for use in spreading dental resin on a tooth during application of tooth shade material.
F.3165	Precision attachment	1	A precision attachment or preformed bar is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended for use in prosthetic dentistry in conjunction with removable partial dentures. Various forms of the device are intended to connect a lower partial denture with another lower partial denture, to connect an upper partial denture with another upper partial denture, to connect either an upper or lower partial denture to a tooth or a crown, or to connect a fixed bridge to a partial denture.
F.3200	Resin tooth bonding agent	2	A resin tooth bonding agent is a device material, such as methylmethacrylate, intended to be painted on the interior of a prepared cavity of a tooth to improve retention of a restoration, such as a filling.
F.3220	Facebow	1	A facebow is a device intended for use in denture fabrication to determine the spatial relationship between the upper and lower jaws. This determination is intended for use in placing denture casts accurately into an articulator and thereby aiding correct placement of artificial teeth into a denture base.

F.3240	Dental bur	1	A dental bur is a rotary cutting device made from carbon steel or tungsten carbide intended to cut hard structures in the mouth, such as teeth or bone. It is also intended to cut hard metals, plastics, porcelains, and similar materials intended for use in the fabrication of dental devices.
F.3250	Calcium hydroxide cavity liner	2	A calcium hydroxide cavity liner is a device material intended to be applied to the interior of a prepared cavity before insertion of restorative material, such as amalgam, to protect the pulp of a tooth.
F.3260	Cavity varnish	2	Cavity varnish is a device that consists of a compound intended to coat a prepared cavity of a tooth before insertion of restorative materials. The device is intended to prevent penetration of restorative materials, such as amalgam, into the dentinal tissue.
F.3275	Dental cement	1,2	Dental cement is a device intended to serve as a temporary tooth filling or as a base cement to affix a temporary tooth filling, to affix dental devices such as crowns or bridges, or to be applied to a tooth to protect the tooth pulp. This device is made by zinc oxide-eugenol. Classification: (1)Class 1: The main component is Zinc oxide-eugenol；(2)Class 2: The main component is Dental cement other than zinc oxide-eugenol.
F.3285	Preformed clasp	1	A preformed clasp or a preformed wire clasp is a prefabricated device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be incorporated into a dental appliance, such as a partial denture, to help stabilize the appliance in the patient's mouth by fastening the appliance to an adjacent tooth.
F.3300	Hydrophilic resin coating for dentures	2	A hydrophilic resin coating for dentures is a device that consists of a water-retaining polymer that is intended to be applied to the base of a denture before the denture is inserted into the patient's mouth to improve denture retention and comfort.
F.3310	Coating material for resin fillings	2	A coating material for resin fillings is a device intended to be applied to the surface of a restorative resin dental filling to attain a smooth, glaze-like finish on the surface of the filling.
F.3330	Preformed crown	1	A preformed crown is a prefabricated device made of plastic or austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be affixed temporarily to a tooth after removal of, or breakage of, the natural crown (that portion of the tooth that normally protrudes above the gums). It is intended for use as a functional restoration until a permanent crown is constructed. The device also may be intended for use as a functional restoration for a badly decayed deciduous (baby) tooth until the adult tooth erupts.
F.3350	Gold or stainless steel cusp	1	A gold or stainless steel cusp is a prefabricated device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group or stainless steel intended to provide a permanent cusp (a projection on the chewing surface of a tooth) to achieve occlusal harmony (a proper bite) between the teeth and a removable denture.

F.3360	Preformed cusp	1	A performed cusp is a prefabricated device made of plastic or austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be used as a temporary cusp (a projection on the chewing surface of a tooth) to achieve occlusal harmony (a proper bite) before permanent restoration of a tooth.
F.3400	Karaya and sodium borate with or without acacia denture adhesive	1,3	A karaya and sodium borate with or without acacia denture adhesive is a device composed of karaya and sodium borate with or without acacia intended to be applied to the base of a denture before the denture is inserted into patient's mouth to improve denture retention and comfort. (1)Classification: Class 1 the device contains less than 12 percent by weight of sodium borate. ; (2)Class 3 the device contains 12 percent or more by weight of sodium borate.
F.3410	Ethylene oxide homopolymer and/or carboxymethyl-cellulose sodium denture adhesive	1	An ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive is a device containing ethylene oxide homopolymer and/or carboxymethylcellulose sodium intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.
F.3420	Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive	3	A carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive is a device composed of carboxymethylcellulose sodium and cationic polyacrylamide polymer intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.
F.3450	Ethylene oxide homopolymer and/or karaya denture adhesive	1	Ethylene oxide homopolymer and/or karaya denture adhesive is a device composed of ethylene oxide homopolymer and/or karaya intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.
F.3480	Polyacrylamide polymer (modified cationic) denture adhesive	3	A polyacrylamide polymer (modified cationic) denture adhesive is a device composed of polyacrylamide polymer (modified cationic) intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.
F.3490	Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive	1	A carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive is a device composed of carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.
F.3500	Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive)	3	Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive is a device composed of polyvinylmethylether maleic anhydride, acid copolymer, and carboxymethylcellulose sodium intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.
F.3520	OTC dental appliance cleanser	1	An OTC dental appliance cleanser is a device that consists of material in the form of a powder, tablet, or paste that is intended to remove debris from removable prosthetic dental appliances, such as bridges , dentures, braces, and retainers. The dental appliance is removed from the patient's mouth when the appliance is cleaned.

F.3540	OTC denture cushion or pad	1,2	An OTC denture cushion or pad is a prefabricated or noncustom made disposable device that is intended to improve the fit of a loose or uncomfortable denture, and may be available for purchase over-the-counter. Classification:(1)Class 1 the device is made of wax-impregnated cotton cloth that the patient applies to the base or inner surface of a denture before inserting the denture into the mouth. (2)Class 2 if the OTC denture cushion or pad is made of a material other than wax-impregnated cotton cloth or if the intended use of the device differs from that described in paragraph (1).
F.3560	OTC denture reliner	2	An OTC denture reliner is a device consisting of a material such as plastic resin that is intended to be applied as a permanent coating or lining on the base or tissue-contacting surface of a denture. The device is intended to replace a worn denture lining and may be available for purchase over the counter.
F.3570	OTC denture repair kit	2	An OTC denture repair kit is a device consisting of a material, such as a resin monomer system of powder and liquid glues, that is intended to be applied permanently to a denture to mend cracks or breaks. The device may be available for purchase over-the counter.
F.3580	Preformed gold denture tooth	1	A preformed gold denture tooth is a device composed of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended for use as a tooth or a portion of a tooth in a fixed or removable partial denture.
F.3590	Preformed plastic denture tooth	2	A preformed plastic denture tooth is a prefabricated device, composed of materials such as methyl methacrylate, that is intended for use as a tooth in a denture.
F.3600	Partially fabricated denture kit	2	A partially fabricated denture kit is a device composed of connected preformed teeth that is intended for use in construction of a denture. A denture base is constructed using the patient's mouth as a mold, by partially polymerizing the resin denture base materials while the materials are in contact with the oral tissues. After the denture base is constructed, the connected preformed teeth are chemically bonded to the base.
F.3630	Endosseous dental implant abutment	2	An endosseous dental implant abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.
F.3640	Endosseous implant	3	An endosseous dental implant is a device made of a material such as titanium or titanium alloy, that is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.
F.3645	Subperiosteal implant material	2	Subperiosteal implant material is a device composed of titanium or cobalt chrome molybdenum intended to construct custom prosthetic devices which are surgically implanted into the lower or upper jaw between the periosteum (connective tissue covering the bone) and supporting bony structures. The device is intended to provide support for prostheses, such as dentures.

F.3660	Impression material	2	Impression material is a device composed of materials such as alginate or polysulfide intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums. The device is intended to provide models for study and for production of restorative prosthetic devices, such as gold inlays and dentures.
F.3661	Optical Impression Systems for CAD/CAM	1	An optical impression system for computer assisted design and manufacturing (CAD/CAM) is a device used to record the topographical characteristics of teeth, dental impressions, or stone models by analog or digital methods for use in the computer-assisted design and manufacturing of dental restorative prosthetic devices. Such systems may consist of a camera, scanner, or equivalent type of sensor and a computer with software.
F.3670	Resin impression tray material	1	Resin impression tray material is a device intended for use in a two-step dental mold fabricating process. The device consists of a resin material, such as methyl methacrylate, and is used to form a custom impression tray for use in cases in which a preformed impression tray is not suitable, such as the fabrication of crowns, bridges, or full dentures. A preliminary plaster or stone model of the patient's teeth and gums is made. The resin impression tray material is applied to this preliminary study model to form a custom tray. This tray is then filled with impression material and inserted into the patient's mouth to make an impression, from which a final, more precise, model of the patient's mouth is cast.
F.3680	Polytetrafluoroethylene (PTFE) vitreous carbon material	2	Polytetrafluoroethylene (PTFE) vitreous carbon material is a device composed of polytetrafluoroethylene (PTFE) vitreous carbon intended for use in maxillofacial alveolar ridge augmentation (building up the upper or lower jaw area that contains the sockets in which teeth are rooted) or intended to coat metal surgical implants to be placed in the alveoli (sockets in which the teeth are rooted) or the temporomandibular joints (the joint between the upper and lower jaws).
F.3690	Tooth shade resin material	2	Tooth shade resin material is a device composed of materials such as bisphenol-A glycidyl methacrylate (Bis-GMA) intended to restore carious lesions or structural defects in teeth.
F.3710	Base metal alloy	2	A base metal alloy is a device composed primarily of base metals, such as nickel, chromium, or cobalt, that is intended for use in fabrication of cast or porcelain-fused-to-metal crown and bridge restorations.
F.3740	Retentive and splinting pin	1	A retentive and splinting pin is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be placed permanently in a tooth to provide retention and stabilization for a restoration, such as a crown, or to join two or more teeth together.
F.3750	Bracket adhesive resin and tooth conditioner	2	A bracket adhesive resin and tooth conditioner is a device composed of an adhesive compound, such as polymethylmethacrylate, intended to cement an orthodontic bracket to a tooth surface.
F.3760	Denture relining, repairing, or rebasing resin	2	A denture relining, repairing, or rebasing resin is a device composed of materials such as methylmethacrylate, intended to reline a denture surface that contacts tissue, to repair a fractured denture, or to form a new denture base. This device is not available for over-the-counter (OTC) use.

F.3765	Pit and fissure sealant and conditioner	2	A pit and fissure sealant and conditioner is a device composed of resin, such as polymethylmethacrylate, intended for use primarily in young children to seal pit and fissure depressions (faults in the enamel) in the biting surfaces of teeth to prevent cavities.
F.3770	Temporary crown and bridge resin	2	A temporary crown and bridge resin is a device composed of a material, such as polymethylmethacrylate, intended to make a temporary prosthesis, such as a crown or bridge, for use until a permanent restoration is fabricated.
F.3810	Root canal post	1	A root canal post is a device made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to be cemented into the root canal of a tooth to stabilize and support a restoration.
F.3820	Root canal filling resin	2,3	A root canal filling resin is a device composed of material, such as methylmethacrylate, intended for use during endodontic therapy to fill the root canal of a tooth.
F.3830	Endodontic paper point	1	An endodontic paper point is a device made of paper intended for use during endodontic therapy to dry, or apply medication to, the root canal of a tooth.
F.3840	Endodontic silver point	1	An endodontic silver point is a device made of silver intended for use during endodontic therapy to fill permanently the root canal of a tooth.
F.3850	Gutta percha	1	Gutta percha is a device made from coagulated sap of certain tropical trees intended to fill the root canal of a tooth. The gutta percha is softened by heat and inserted into the root canal, where it hardens as it cools.
F.3890	Endodontic stabilizing splint	2	An endodontic stabilizing splint is a device made of a material, such as titanium, intended to be inserted through the root canal into the upper or lower jaw bone to stabilize a tooth.
F.3900	Posterior artificial tooth with a metal insert	1	A posterior artificial tooth with a metal insert is a porcelain device with an insert made of austenitic alloys or alloys containing 75 percent or greater gold and metals of the platinum group intended to replace a natural tooth. The device is attached to surrounding teeth by a bridge and is intended to provide both an improvement in appearance and functional occlusion (bite).
F.3910	Backing and facing for an artificial tooth	1	A backing and facing for an artificial tooth is a device intended for use in fabrication of a fixed or removable dental appliance, such as a crown or bridge. The backing, which is made of gold, is attached to the dental appliance and supports the tooth-colored facing, which is made of porcelain or plastic.
F.3920	Porcelain tooth	2	A porcelain tooth is a prefabricated device made of porcelain powder for clinical use (F.6660) intended for use in construction of fixed or removable prostheses, such as crowns and partial dentures.
F.3930	Tricalcium phosphate granules for dental bone repair	2,3	Bone grafting material is a material such as hydroxyapatite, tricalcium phosphate, polylactic and polyglycolic acids, or collagen, that is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region. Classification:(1)Class 2 devices do not contain medicine.; (2) Class 3 devices contain medicine.

F.3940	Total temporomandibular joint prosthesis	3	A total temporomandibular joint prosthesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and augment the glenoid fossa to functionally reconstruct the temporomandibular joint.
F.3950	Glenoid fossa prosthesis	3	A glenoid fossa prosthesis is a device that is intended to be implanted in the temporomandibular joint to augment a glenoid fossa or to provide an articulation surface for the head of a mandibular condyle.
F.3960	Mandibular condyle prosthesis	3	A mandibular condyle prosthesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and to articulate within a glenoid fossa.
F.3970	Interarticular disc prosthesis (interpositional implant)	3	An interarticular disc prosthesis (interpositional implant) is a device that is intended to be an interface between the natural articulating surface of the mandibular condyle and glenoid fossa.
F.3980	Endosseous dental implant accessories	1	Endosseous dental implant accessories are manually powered devices intended to aid in the placement or removal of endosseous dental implants and abutments, prepare the site for placement of endosseous dental implants or abutments, aid in the fitting of endosseous dental implants or abutments, aid in the fabrication of dental prosthetics, and be used as an accessory with endosseous dental implants when tissue contact will last less than 1 hour. These devices include drill bits, screwdrivers, countertorque devices, placement and removal tools, laboratory pieces used for fabrication of dental prosthetics, and trial abutments.
F.4120	Bone cutting instrument and accessories	2	A bone cutting instrument and accessories is a metal device intended for use in reconstructive oral surgery to drill or cut into the upper or lower jaw and may be used to prepare bone to insert a wire, pin, or screw. The device includes the manual bone drill and wire driver, powered bone drill, rotary bone cutting handpiece, and AC-powered bone saw.
F.4130	Intraoral dental drill	1	An intraoral dental drill is a rotary device intended to be attached to a dental handpiece to drill holes in teeth to secure cast or preformed pins to retain operative dental appliances.
F.4200	Dental handpiece and accessories	1	A dental handpiece and accessories is an AC-powered, water-powered, air-powered, or belt-driven, hand-held device that may include a foot controller for regulation of speed and direction of rotation or a contra-angle attachment for difficult to reach areas intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.
F.4465	Gas-powered jet injector	2	A gas-powered jet injector is a syringe device intended to administer a local anesthetic. The syringe is powered by a cartridge containing pressurized carbon dioxide which provides the pressure to force the anesthetic out of the syringe.
F.4475	Spring-powered jet injector	2	A spring-powered jet injector is a syringe device intended to administer a local anesthetic. The syringe is powered by a spring mechanism which provides the pressure to force the anesthetic out of the syringe.

F.4535	Dental diamond instrument	1	A dental diamond instrument is an abrasive device intended to smooth tooth surfaces during the fitting of crowns or bridges. The device consists of a shaft which is inserted into a handpiece and a head which has diamond chips imbedded into it. Rotation of the diamond instrument provides an abrasive action when it contacts a tooth.
F.4565	Dental hand instrument	1	A dental hand instrument is a hand-held device intended to perform various tasks in general dentistry and oral surgery procedures. The device includes the operative burnisher, operative amalgam carrier, operative dental amalgam carver, surgical bone chisel, operative amalgam and foil condenser, endodontic curette, operative curette, periodontic curette, surgical curette, dental surgical elevator, operative dental excavator, operative explorer surgical bone file, operative margin finishing file, periodontic file, periodontic probe, surgical rongeur forceps, surgical tooth extractor forceps, surgical hemostat, periodontic hoe, operative matrix contouring instrument, operative cutting instrument, operative margin finishing periodontic knife, periodontic marker, operative pliers, endodontic root canal plugger, endodontic root canal preparer, surgical biopsy punch, endodontic pulp canal reamer, crown remover, periodontic scaler, collar and crown scissors, endodontic pulp canal filling material spreader, surgical osteotome chisel, endodontic broach, dental wax carver, endodontic pulp canal file, hand instrument for calculus removal, dental depth gauge instrument, plastic dental filling instrument, dental instrument handle, surgical tissue scissors, mouth mirror, orthodontic band driver, orthodontic band pusher, orthodontic band setter, orthodontic bracket aligner, orthodontic pliers, orthodontic ligature tucking instrument, forceps, for articulation paper, forceps for dental dressing, dental matrix band, matrix retainer, dental retractor, dental retractor accessories, periodontic or endodontic irrigating syringe, and restorative or impression material syringe.
F.4600	Intraoral ligature and wire lock	2	An intraoral ligature and wire lock is a metal device intended to constrict fractured bone segments in the oral cavity. The bone segments are stabilized by wrapping the ligature (wire) around the fractured bone segments and locking the ends together.
F.4620	Fiber optic dental light	1	A fiber optic dental light is a device that is a light, usually AC-powered, that consists of glass or plastic fibers which have special optical properties. The device is usually attached to a dental handpiece and is intended to illuminate a patient's oral structures.
F.4630	Dental operating light	1	A dental operating light, including the surgical headlight, is an AC-powered device intended to illuminate oral structures and operating areas.
F.4730	Dental injecting needle	1	A dental injecting needle is a slender, hollow metal device with a sharp point intended to be attached to a syringe to inject local anesthetics and other drugs.
F.4760	Bone plate	2	A bone plate is a metal device intended to stabilize fractured bone structures in the oral cavity. The bone segments are attached to the plate with screws to prevent movement of the segments.

F.4770	Temporary mandibular condyle reconstruction plate	2	A temporary mandibular condyle reconstruction plate is a device that is intended to stabilize mandibular bone and provide for temporary reconstruction of the mandibular condyle until permanent reconstruction is completed in patients who have undergone respective surgical procedures requiring removal of the mandibular condyle and mandibular bone. This device is not intended for treatment of temporomandibular joint disorders.
F.4840	Rotary scaler	2	A rotary scaler is an abrasive device intended to be attached to a powered handpiece to remove calculus deposits from teeth during dental cleaning and periodontal (gum) therapy.
F.4850	Ultrasonic scaler	2	An ultrasonic scaler is a device intended for use during dental cleaning and periodontal (gum) therapy to remove calculus deposits from teeth by application of an ultrasonic vibrating scaler tip to the teeth.
F.4880	Intraosseous fixation screw or wire	2	An intraosseous fixation screw or wire is a metal device intended to be inserted into fractured jaw bone segments to prevent their movement.
F.4920	Dental electrosurgical unit and accessories	2	A dental electrosurgical unit and accessories is an AC-powered device consisting of a controlled power source and a set of cutting and coagulating electrodes. This device is intended to cut or remove soft tissue or to control bleeding during surgical procedures in the oral cavity. An electrical current passes through the tip of the electrode into the tissue and, depending upon the operating mode selected, cuts through soft tissue or coagulates the tissue.
F.5410	Orthodontic appliance and accessories	1	An orthodontic appliance and accessories is a device intended for use in orthodontic treatment. The device is affixed to a tooth so that pressure can be exerted on the teeth. This device includes the preformed orthodontic band, orthodontic band material, orthodontic elastic band, orthodontic metal bracket, orthodontic wire clamp, preformed orthodontic space maintainer, orthodontic expansion screw retainer, orthodontic spring, orthodontic tube, and orthodontic wire.
F.5470	Orthodontic plastic bracket	2	An orthodontic plastic bracket is a plastic device intended to be bonded to a tooth to apply pressure to a tooth from a flexible orthodontic wire to alter its position.
F.5500	Extraoral orthodontic headgear	2	An extraoral orthodontic headgear is a device intended for use with an orthodontic appliance to exert pressure on the teeth from outside the mouth. The headgear has a strap intended to wrap around the patient's neck or head and an inner bow portion intended to be fastened to the orthodontic appliance in the patient's mouth.
F.5525	Preformed tooth positioner	1	A preformed tooth positioner is a plastic device that is made for an impression of a bite intended to prevent a patient's teeth from shifting position or to maintain teeth in a final position after orthodontic appliances (braces) have been removed. The patient bites down on the device for several hours a day to stabilize the position of the teeth.
F.5560	Electrical salivary stimulatory system	2	An electrical salivary stimulatory system is a prescription intraoral device that is intended to electrically stimulate a relative increase in saliva production.

F.5570	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea	2	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea are devices that are worn during sleep to reduce the incidence of snoring and to treat obstructive sleep apnea. The devices are designed to increase the patency of the airway and to decrease air turbulence and airway obstruction. The classification includes palatal lifting devices, tongue retaining devices, and mandibular repositioning devices.
F.6010	Abrasive device and accessories	1	An abrasive device and accessories is a device constructed of various abrasives, such as diamond chips, that are glued to shellac-based paper. The device is intended to remove excessive restorative materials, such as gold, and to smooth rough surfaces from oral restorations, such as crowns. The device is attached to a shank that is held by a handpiece. The device includes the abrasive disk, guard for an abrasive disk, abrasive point, polishing agent strip, and polishing wheel.
F.6030	Oral cavity abrasive polishing agent	1	An oral cavity abrasive polishing agent is a device in paste or powder form that contains an abrasive material, such as silica pumice, intended to remove debris from the teeth. The abrasive polish is applied to the teeth by a handpiece attachment (prophylaxis cup).
F.6050	Saliva absorber	1	A saliva absorber is a device made of paper or cotton intended to absorb moisture from the oral cavity during dental procedures.
F.6070	Ultraviolet activator for polymerization	2	An ultraviolet activator for polymerization is a device that produces ultraviolet radiation intended to polymerize (set) resinous dental pit and fissure sealants or restorative materials by transmission of light through a rod.
F.6080	Airbrush	2	An airbrush is an AC-powered device intended for use in conjunction with articulation paper. The device uses air-driven particles to roughen the surfaces of dental restorations. Uneven areas of the restorations are then identified by use of articulation paper.
F.6100	Anesthetic warmer	1	An anesthetic warmer is an AC-powered device into which tubes containing anesthetic solution are intended to be placed to warm them prior to administration of the anesthetic.
F.6140	Articulation paper	1	Articulation paper is a device composed of paper coated with an ink dye intended to be placed between the patient's upper and lower teeth when the teeth are in the bite position to locate uneven or high areas.
F.6200	Base plate shellac	1	Base plant shellac is a device composed of shellac intended to rebuild the occlusal rim of full or partial dentures.
F.6250	Dental chair and accessories	1	A dental chair and accessories is a device, usually AC-powered, in which a patient sits. The device is intended to properly position a patient to perform dental procedures. A dental operative unit may be attached.
F.6290	Prophylaxis cup	1	A prophylaxis cup is a device made of rubber intended to be held by a dental handpiece and used to apply polishing agents during prophylaxis (cleaning). The dental handpiece spins the rubber cup holding the polishing agent and the user applies it to the teeth to remove debris.

F.6300	Rubber dam and accessories	1	A rubber dam and accessories is a device composed of a thin sheet of latex with a hole in the center intended to isolate a tooth from fluids in the mouth during dental procedures, such as filling a cavity preparation. The device is stretched around a tooth by inserting a tooth through a hole in the center. The device includes the rubber dam, rubber dam clamp, rubber dam frame, and forceps for a rubber dam clamp. This classification does not include devices intended for use in preventing transmission of sexually transmitted diseases through oral sex; those devices are classified as condoms in 884.5300 of this chapter.
F.6350	Ultraviolet detector	2	An ultraviolet detector is a device intended to provide a source of ultraviolet light which is used to identify otherwise invisible material, such as dental plaque, present in or on teeth.
F.6475	Heat source for bleaching teeth	1	A heat source for bleaching teeth is a device that consists of a light or an electric heater intended to apply heat to a tooth after it is treated with a bleaching agent.
F.6570	Impression tube	1	An impression tube is a device consisting of a hollow copper tube intended to take an impression of a single tooth. The hollow tube is filled with impression material. One end of the tube is sealed with a softened material, such as wax, the remaining end is slipped over the tooth to make the impression.
F.6640	Dental operative unit and accessories	1	A dental operative unit and accessories is an AC-powered device that is intended to supply power to and serve as a base for other dental devices, such as a dental handpiece, a dental operating light, an air or water syringe unit, and oral cavity evacuator, a suction operative unit, and other dental devices and accessories. The device may be attached to a dental chair.
F.6660	Porcelain powder for clinical use	2	Porcelain powder for clinical use is a device consisting of a mixture of kaolin, felspar, quartz, or other substances intended for use in the production of artificial teeth in fixed or removable dentures, of jacket crowns, facings, and veneers. The device is used in prosthetic dentistry by heating the powder mixture to a high temperature in an oven to produce a hard prosthesis with a glass-like finish.
F.6710	Boiling water sterilizer	1	A boiling water sterilizer is an AC-powered device that consists of a container for boiling water. The device is intended to sterilize dental and surgical instruments by submersion in the boiling water in the container.
F.6730	Endodontic dry heat sterilizer	3	An endodontic dry heat sterilizer is a device intended to sterilize endodontic and other dental instruments by the application of dry heat. The heat is supplied through glass beads which have been heated by electricity.
F.6770	Cartridge syringe	2	A cartridge syringe is a device intended to inject anesthetic agents subcutaneously or intramuscularly. The device consists of a metal syringe body into which a disposable, previously filled, glass carpule (a cylindrical cartridge) containing anesthetic is placed. After attaching a needle to the syringe body and activating the carpule by partially inserting the plunger on the syringe, the device is used to administer an injection to the patient.
F.6870	Disposable fluoride tray	1	A disposable fluoride tray is a device made of styrofoam intended to apply fluoride topically to the teeth. To use the tray, the patient bites down on the tray which has been filled with a fluoride solution.

F.6880	Preformed impression tray	1	A preformed impression tray is a metal or plastic device intended to hold impression material, such as alginate, to make an impression of a patient's teeth or alveolar process (bony tooth sockets) to reproduce the structure of a patient's teeth and gums.
F.6890	Intraoral dental wax	1	Intraoral dental wax is a device made of wax intended to construct patterns from which custom made metal dental prostheses, such as crowns and bridges, are cast. In orthodontic dentistry, the device is intended to make a pattern of a patient's bite to make study models of the teeth.
F.9999	Others(Dental Devices)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.
G.0001	Cochlear implant	3	A cochlear implant establishes hearing capability for a hearing impaired patient by using electrical signals (e.g., electrical currents, etc.) to stimulate auditory nerve.
G.1050	Audiometer	1,2	An audiometer or automated audiometer is an electroacoustic device that produces controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders.Classification: (1) Class I ;(2) Class II: otoacoustic emission device.
G.1070	Short increment sensitivity index (SISI) adapter	1	A short increment sensitivity index (SISI) adapter is a device used with an audiometer in diagnostic hearing evaluations. A SISI adapter provides short periodic sound pulses in specific small decibel increments that are intended to be superimposed on the audiometer's output tone frequency.
G.1090	Auditory impedance tester	2	An auditory impedance tester is a device that is intended to change the air pressure in the external auditory canal and measure and graph the mobility characteristics of the tympanic membrane to evaluate the functional condition of the middle ear. The device is used to determine abnormalities in the mobility of the tympanic membrane due to stiffness, flaccidity, or the presence of fluid in the middle ear cavity. The device is also used to measure the acoustic reflex threshold from contractions of the stapedial muscle, to monitor healing of tympanic membrane grafts or stapedectomies, or to monitor followup treatment for inflammation of the middle ear.
G.1100	Earphone cushion for audiometric testing	1	An earphone cushion for audiometric testing is a device that is used to cover an audiometer earphone during audiometric testing to provide an acoustic coupling (sound connection path) between the audiometer earphone and the patient's ear.
G.1120	Electronic noise generator for audiometric testing	2	An electronic noise generator for audiometric testing is a device that consists of a swept frequency generator, an amplifier, and an earphone. It is intended to introduce a masking noise into the non-test ear during an audiometric evaluation. The device minimizes the non-test ear's sensing of test tones and signals being generated for the ear being tested.

G.1325	Electroglottograph	2	An electroglottograph is an AC-powered device that employs a pair of electrodes that are placed in contact with the skin on both sides of the larynx and held in place by a collar. It is intended to measure the electrical impedance of the larynx to aid in assessing the degree of closure of the vocal cords, confirm larygeal diagnosis, aid behavioral treatment of voice disorders, and aid research concerning the laryngeal mechanism.
G.1500	Gustometer	1	A gustometer is a battery-powered device that consists of two electrodes that are intended to be placed on both sides of the tongue at different taste centers and that provides a galvanic stimulus resulting in taste sensation. It is used for assessing the sense of taste.
G.1600	Olfactory test device	1	An olfactory test device is used to determine whether an olfactory loss is present. The device includes one or more odorants that are presented to the patient's nose to subjectively assess the patient's ability to perceive odors.
G.1800	Air or water caloric stimulator	1	An air or water caloric stimulator is a device that delivers a stream of air or water to the ear canal at controlled rates of flow and temperature and that is intended for vestibular function testing of a patient's body balance system. The vestibular stimulation of the semicircular canals produce involuntary eye movements that are measured and recorded by a nystagmograph.
G.1820	Surgical nerve stimulator/locator	2	A surgical nerve stimulator/locator is a device that is intended to provide electrical stimulation to the body to locate and identify nerves and to test their excitability.
G.1925	Toynbee diagnostic tube	1	The toynbee diagnostic tube is a listening device intended to determine the degree of openness of the eustachian tube.
G.3300	Hearing aid	1,2	A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400).
G.3310	Hearing aid calibrator and analysis system	2	A hearing aid calibrator and analysis system is an electronic reference device intended to calibrate and assess the electroacoustic frequency and sound intensity characteristics emanating from a hearing aid, master hearing aid, group hearing aid or group auditory trainer. The device consists of an acoustic complex of known cavity volume, a sound level meter, a microphone, oscillators, frequency counters, microphone amplifiers, a distoration analyzer, a chart recorder, and a hearing aid test box.
G.3315	Tympanic membrane contact hearing aid	2	A tympanic membrane contact hearing aid is a prescription device that compensates for impaired hearing. Amplified sound is transmitted by vibrating the tympanic membrane through a transducer that is in direct contact with the tympanic membrane.

G.3320	Group hearing aid or group auditory trainer	2	A group hearing aid or group auditory trainer is a hearing aid that is intended for use in communicating simultaneously with one or more listeners having hearing impairment. The device is used with an associated transmitter microphone. It may be either monaural or binaural, and it provides coupling to the ear through either earphones or earmolds. The generic type of device includes three types of applications: hardwire systems, inductance loop systems, and wireless systems.
G.3330	Master hearing aid	2	A master hearing aid is an electronic device intended to simulate a hearing aid during audiometric testing. It has adjustable acoustic output levels, such as those for gain, output, and frequency response. The device is used to select and adjust a person's wearable hearing aid.
G.3400	Tinnitius masker	2	A tinnitus masker is an electronic device intended to generate noise of sufficient intensity and bandwidth to mask ringing in the ears or internal head noises. Because the device is able to mask internal noises, it is also used as an aid in hearing external noises and speech.
G.3430	Middle ear mold	2	A middle ear mold is a preformed device that is intended to be implanted to reconstruct the middle ear cavity during repair of the tympanic membrane. The device permits an ample air-filled cavity to be maintained in the middle ear and promotes regeneration of the mucous membrane lining of the middle ear cavity. A middle ear mold is made of materials such as polyamide, polytetrafluoroethylene, silicone elastomer, or polyethylene, but does not contain porous polyethylene.
G.3450	Partial ossicular replacement prosthesis	2	A partial ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear. The device is made of materials such as stainless steel, tantalum, polytetrafluoroethylene, polyethylene, polytetrafluoroethylene with carbon fibers composite, absorbable gelatin material, porous polyethylene, or from a combination of these materials.
G.3495	Total ossicular replacement prosthesis	2	A total ossicular replacement prosthesis is a device intended to be implanted for the total functional reconstruction of the ossicular chain and facilitates the conduction of sound waves from the tympanic membrance to the inner ear. The device is made of materials such as polytetrafluoroethylene, polytetrafluoroethylene with vitreous carbon fibers composite, porous polyethylene, or from a combination of these materials.
G.3540	Prosthesis modification instrument for ossicular replacement surgery	1	A prosthesis modification instrument for ossicular replacement surgery is a device intended for use by a surgeon to construct ossicular replacements. This generic type of device includes the ear, nose, and throat cutting block; wire crimper, wire bending die; wire closure forceps; piston cutting jib; gelfoamTMpunch; wire cutting scissors; and ossicular finger vise.

G.3620	Ear, nose, and throat synthetic polymer material	2	Ear, nose, and throat synthetic polymer material is a device material that is intended to be implanted for use as a space-occupying substance in the reconstructive surgery of the head and neck. The device is used, for example, in augmentation rhinoplasty and in tissue defect closures in the esophagus. The device is shaped and formed by the suregon to conform to the patient's needs. This generic type of device is made of material such as polyamide mesh or foil and porous polyethylene.
G.3695	Mandibular implant facial prosthesis	2	A mandibular implant facial prosthesis is a device that is intended to be implanted for use in the functional reconstruction of mandibular deficits. The device is made of materials such as stainless steel, tantalum, titanium, cobalt-chromium based alloy, polytetrafluoroethylene, silicone elastomer, polyethylene, polyurethane, or polytetrafluoroethylene with carbon fibers composite.
G.3730	Laryngeal prosthesis (Taub design)	2	A laryngeal prosthesis (Taub design) is a device intended to direct pulmonary air flow to the pharynx in the absence of the larynx, thereby permitting esophageal speech. The device is interposed between openings in the trachea and the esophagus and may be removed and replaced each day by the patient. During phonation, air from the lungs is directed to flow through the device and over the esophageal mucosa to provide a sound source that is articulated as speech.
G.3760	Sacculotomy tack (Cody tack)	2	A sacculotomy tack (Cody tack) is a device that consists of a pointed stainless steel tack intended to be implanted to relieve the symptoms of vertigo. The device repetitively ruptures the utricular membrane as the membrane expands under increased endolymphatic pressure.
G.3820	Endolymphatic shunt	2	An endolymphatic shunt is a device that consists of a tube or sheet intended to be implanted to relieve the symptons of vertigo. The device permits the unrestricted flow of excess endolymph from the distended end of the endolymphatic system into the mastoid cavity where resorption occurs. This device is made of polytetrafluoroethylene or silicone elastomer.
G.3850	Endolymphatic shunt tube with valve	2	An endolymphatic shunt tube with valve is a device that consists of a pressure-limiting valve associated with a tube intended to be implanted in the inner ear to relieve symptoms of vertigo and hearing loss due to endolymphatic hydrops (increase in endolymphatic fluid) of Meniere's disease.
G.3880	Tympanostomy tube	2	A tympanostomy tube is a device that is intended to be implanted for ventilation or drainage of the middle ear. The device is inserted through the tympanic membrane to permit a free exchange of air between the outer ear and middle ear. A type of tympanostomy tube known as the malleous clip tube attaches to the malleous to provide middle ear ventilation. The device is made of materials such as polytetrafluoroethylene, polyethylene, silicon elastomer, or porous polyethylene.

G.3900	Nasal dilator	1	A nasal dilator is a device intended to provide temporary relief from transient causes of breathing difficulties resulting from structural abnormalities and/or transient causes of nasal congestion associated with reduced nasal airflow. The device decreases airway resistance and increases nasal airflow. The external nasal dilator is constructed from one or more layers of material upon which a spring material is attached, with a skin adhesive applied to adhere to the skin of the nose; it acts with a pulling action to open the nares. The internal nasal dilator is constructed from metal or plastic and is placed inside the nostrils; it acts by pushing the nostrils open or by gently pressing on the columella.
G.3930	Tympanostomy tube with semipermeable membrane	2	A tympanostomy tube with a semipermeable membrane is a device intended to be implanted for ventilation or drainage of the middle ear and for preventing fluids from entering the middle ear cavity. The device is inserted through the tympanic membrane to permit a free exchange of air between the outer ear and middle ear. The tube portion of the device is made of silicone elastomer or porous polyethylene, and the membrane portion is made of polytetrafluoroethylene.
G.3950	Transcutaneous air conduction hearing aid system	2	A transcutaneous air conduction hearing aid system is a wearable sound-amplifying device intended to compensate for impaired hearing without occluding the ear canal. The device consists of an air conduction hearing aid attached to a surgically fitted tube system, which is placed through soft tissue between the post auricular region and the outer ear canal.
G.4100	Epistaxis balloon	1	An epistaxis balloon is a device consisting of an inflatable balloon intended to control internal nasal bleeding by exerting pressure against the sphenopalatine artery.
G.4140	Ear, nose, and throat bur	1	An ear, nose, and throat bur is a device consisting of an interchangeable drill bit that is intended for use in an ear, nose, and throat electric or pneumatic surgical drill (874.4250) for incising or removing bone in the ear, nose, or throat area. The bur consists of a carbide cutting tip on a metal shank or a coating of diamond on a metal shank. The device is used in mastoid surgery, frontal sinus surgery, and surgery of the facial nerves.
G.4175	Nasopharyngeal catheter	1	A nasopharyngeal catheter is a device consisting of a bougie or filiform catheter that is intended for use in probing or dilating the eustachian tube. This generic type of device includes eustachian catheters.
G.4180	Eustachian tube balloon dilation system	2	A Eustachian tube balloon dilation system is a prescription device that includes a flexible catheter attached to an inflatable balloon. The system is intended for use in dilating the cartilaginous portion of the Eustachian tube for treating persistent Eustachian tube dysfunction.
G.4250	Ear, nose, and throat electric or pneumatic surgical drill	2	An ear, nose, and throat electric or pneumatic surgical drill is a rotating drilling device, including the handpiece, that is intended to drive various accessories, such as an ear, nose, and throat bur (874.4140), for the controlled incision or removal of bone in the ear, nose, and throat area.

G.4350	Ear, nose, and throat fiberoptic light source and carrier	1	An ear, nose, and throat fiberoptic light source and carrier is an AC-powered device that generates and transmits light through glass of plastic fibers and that is intended to provide illumination at the tip of an ear, nose, or throat endoscope. Endoscopic devices which utilize fiberoptic light sources and carriers include the bronchoscope, esophagoscope, laryngoscope, mediastinoscope, laryngeal-bronchial telescope, and nasopharyngoscope.
G.4420	Ear, nose, and throat manual surgical instrument	1	An ear, nose, and throat manual surgical instrument is one of a variety of devices intended for use in surgical procedures to examine or treat the bronchus, esophagus, trachea, larynx, pharynx, nasal and paranasal sinus, or ear. This generic type of device includes the esophageal dilator; tracheal bistour (a long, narrow surgical knife); tracheal dilator; tracheal hook; laryngeal injection set; laryngeal knife; laryngeal saw; laryngeal trocar; laryngectomy tube; adenoid curette; adenotome; metal tongue depressor; mouth gag; oral screw; salpingeal curette; tonsillectome; tonsil guillotine; tonsil screw; tonsil snare; tonsil suction tube; tonsil suturing hook; antom reforator; ethmoid curette; frontal sinus-rasp; nasal curette; nasal rasp; nasal rongeur; nasal saw; nasal scissors; nasal snare; sinus irrigator; sinus trephine; ear curette; ear excavator; ear rasp; ear scissor, ear snare; ear spoon; ear suction tube; malleous ripper; mastoid gauge; microsurgical ear chisel; myringotomy tube inserter; ossici holding clamp; sacculotomy tack inserter; vein press; wire ear loop; microrule; mirror; mobilizer; ear, nose, and throat punch; ear, nose and throat knife; and ear, nose, and throat trocar.
G.4490	Argon laser for otology, rhinology, and laryngology	2	The argon laser device for use in otology, rhinology, and laryngology is an electro-optical device which produces coherent, electromagnetic radiation with principal wavelength peaks of 488 and 514 nanometers. In otology, the device is used for the purpose of coagulating and vaporizing soft and fibrous tissues, including osseous tissue. In rhinology and laryngology, the device is used to coagulate and vaporize soft and fibrous tissues, but not including osseous tissues.
G.4500	Ear, nose, and throat microsurgical carbon dioxide laser	2	An ear, nose, and throat microsurgical carbon dioxide laser is a device intended for the surgical excision of tissue from the ear, nose, and throat area. The device is used, for example, in microsurgical procedures to excise lesions and tumors of the vocal cords and adjacent areas.
G.4680	Bronchoscope (flexible or rigid) and accessories	2	A bronchoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the bronchoscope and is intended to examine or treat the larynx and tracheobronchial tree. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. This generic type of device includes the rigid ventilating bronchoscope, rigid nonventilating bronchoscope, nonrigid bronchoscope, laryngeal-bronchial telescope, flexible foreign body claw, bronchoscope tubing, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, flexible biopsy curette, and rigid bronchoscope aspirating tube, but excludes the fiberoptic light source and carrier.

G.4710	Esophagoscope (flexible or rigid) and accessories	2	An esophagoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the esophagoscope and is intended to examine or treat esophageal malfunction symptoms, esophageal or mediastinal disease, or to remove foreign bodies from the esophagus. When inserted, the device extends from the area of the hypopharynx to the stomach. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. This generic type of device includes the flexible foreign body claw, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps and flexible biopsy curette, but excludes the fiberoptic light source and carrier.
G.4720	Mediastinoscope and accessories	2	A mediastinoscope and accessories is a tubular tapered electrical endoscopic device with any of a group of accessory devices which attach to the mediastinoscope and is intended to examine or treat tissue in the area separating the lungs. The device is inserted transthoracicly and is used in diagnosis of tumors and lesions and to determine whether excision of certain organs or tissues is indicated. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel. This generic type of device includes the flexible foreign body claw, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, and flexible biopsy curette, but excludes the fiberoptic light source and carrier.
G.4750	Laryngostroboscope	1	A laryngostroboscope is a device that is intended to allow observation of glottic action during phonation. The device operates by focusing a stroboscopic light through a lens for direct or mirror reflected viewing of glottic action. The light and microphone that amplifies acoustic signals from the glottic area may or may not contact the patient.
G.4760	Nasopharyngoscope (flexible or rigid) and accessories	2	A nasopharyngoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the nasopharyngoscope and is intended to examine or treat the nasal cavity and nasal pharynx. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel and flexible plastic. This generic type of device includes the antroscope, nasopharyngolaryngoscope, nasosinuscope, nasoscope, postrhinoscope, rhinoscope, salpingoscope, flexible foreign body claw, flexible biopsy forceps, rigid biopsy curette, flexible biospy brush, rigid biopsy forceps and flexible biopsy curette, but excludes the fiberoptic light source and carrier.
G.4770	Otoscope	1	An otoscope is a device intended to allow inspection of the external ear canal and tympanic membrane under magnification. The device provides illumination of the ear canal for observation by using an AC- or battery-powered light source and an optical magnifying system.
G.4780	Intranasal splint	1	An intranasal splint is intended to minimize bleeding and edema and to prevent adhesions between the septum and the nasal cavity. It is placed in the nasal cavity after surgery or trauma. The intranasal splint is constructed from plastic, silicone, or absorbent material.

G.4800	Bone Particle collector	1	A bone particle collector is a filtering device intended to be inserted into a suction tube during the early stages of otologic surgery to collect bone particles for future use.
G.5220	Ear, nose, and throat drug administration device and contained substance	1,2	(a)Identification: An ear, nose, and throat drug administration device is one of a group of ear, nose, and throat devices intended specifically to administer medicinal substances to treat ear, nose, and throat disorders. These instruments include the powder blower, dropper, ear wick, manual nebulizer pump, and nasal inhaler.(b)Classification: Class 1: The device does not contain substance (liquid or other substance),Class 2: The device contains flushing solution, or the substance (solution, solute, powder,etc.) is used in combination with the device to achieve the intended purpose, and the aforementioned solution contained in the device or substance used in combination with the device is not regulated as a medicinal substance.
G.5300	Ear, nose, and throat examination and treatment unit	1	An ear, nose, and throat examination and treatment unit is an AC-powered device intended to support a patient during an otologic examination while providing specialized features for examination and treatment. The unit consists of a patient chair and table, drawers for equipment, suction and blowing apparatus, and receptacles for connection of specialized lights and examining instruments.
G.5350	Suction antichoke device	3	A suction antichoke device is a device intended to be used in an emergency situation to remove, by the application of suction, foreign objects that obstruct a patient's airway to prevent asphyxiation to the patient.
G.5370	Tongs antichoke device	3	A tongs antichoke device is a device that is intended to be used in an emergency situation to grasp and remove foreign objects that obstruct a patient's airway to prevent asphyxiation of the patient. This generic type of device includes a plastic instrument with serrated ends that is inserted into the airway in a blind manner to grasp and extract foreign objects, and a stainless steel forceps with spoon ends that is inserted under tactile guidance to grasp and extract foreign objects from the airway.
G.5550	Powered nasal irrigator	1	A powered nasal irrigator is an AC-powered device intended to wash the nasal cavity by means of a pressure-controlled pulsating stream of water. The device consists of a control unit and pump connected to a spray tube and nozzle.
G.5800	External nasal splint	1	An external nasal splint is a rigid or partially rigid device intended for use externally for immobilization of parts of the nose.
G.5840	Antistammering device	1	An antistammering device is a device that electronically generates a noise when activated or when it senses the user's speech and that is intended to prevent the user from hearing the sounds of his or her own voice. The device is used to minimize a user's involuntary hesitative or repetitive speech.
G.9999	Others(Ear, Nose, and Throat Devices)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.

H.0002	Dialyzer reprocessing system	2	An haemodialysis dialyzer reprocessing system is intended to clean and disinfection of reusable dialyzers. The system may include computing system for operation.
H.0003	Urological Extracorporeal Shock Wave Therapy System	3	An urological extracorporeal shock wave therapy system is a device that can treat urology-related diseases by generating shock waves. This device can be used only by health professionals.
H.1075	Gastroenterology-urology biopsy instrument	1,2	(a) A gastroenterology-urology biopsy instrument is a device used to remove, by cutting or aspiration, a specimen of tissue for microscopic examination. This generic type of device includes the biopsy punch, gastrointestinal mechanical biopsy instrument, suction biopsy instrument, gastro-urology biopsy needle and needle set, and nonelectric biopsy forceps. This section does not apply to biopsy instruments that have been used in other medical specialty areas or covered by biopsy instruments of relevant classification categories.(b) Classification: (1) Class 2, (2) Class 1 for the biopsy forceps cover and the non-electric biopsy forceps.
H.1300	Ingestible telemetric gastro-intestinal capsule imaging system	2	An ingestible telemetric gastrointestinal capsule imaging system is used for visualization of the small bowel mucosa as an adjunctive tool in the detection of abnormalities of the small bowel. The device captures images of the small bowel with a wireless camera contained in a capsule. This device includes an ingestible capsule (containing a light source, camera, transmitter, and battery), an antenna array, a receiving/recording unit, a data storage device, computer software to process the images, and accessories.
H.1330	Colon Capsule Imaging System	2	A prescription, single-use ingestible capsule designed to acquire video images during natural propulsion through the digestive system. It is specifically designed to visualize the colon for the detection of polyps. It is intended for use only in patients who had an incomplete optical colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible.
H.1400	Stomach pH electrode	1	A stomach pH electrode is a device used to measure intragastric and intraesophageal pH (hydrogen ion concentration). The pH electrode is at the end of a flexible lead which may be inserted into the esophagus or stomach through the patient's mouth. The device may include an integral gastrointestinal tube.

H.1500	Endoscope and accessories	1,2	(a) An endoscope and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals. The device consists of various rigid or flexible instruments that are inserted into body spaces and may include an optical system for conveying an image to the user's eye and their accessories may assist in gaining access or increase the versatility and augment the capabilities of the devices. Examples of devices that are within this generic type of device include cleaning accessories for endoscopes, photographic accessories for endoscopes, nonpowered anoscopes, binolcular attachments for endoscopes, pocket battery boxes, flexible or rigid choledochoscopes, colonoscopes, diagnostic cystoscopes, cystourethroscopes, enteroscopes, esophagogastroduodenoscopes, rigid esophagoscopes, fiberoptic illuminators for endoscopes, incandescent endoscope lamps, biliary pancreatoscopes, proctoscopes, resectoscopes, nephroscopes, sigmoidoscopes, ureteroscopes, urethroscopes, endomagnetic retrievers, cytology brushes for endoscopes, biopsy tissue forceps used with endoscopes, and lubricating jelly for transurethral surgical instruments. This section does not apply to endoscopes that have been used in other medical specialty areas or covered by endoscopes of relevant classification categories. (b) Classification: (1) Class 2. (2) Class 1 for the photographic accessories for endoscope, miscellaneous bulb adapter for endoscope, binocular attachment for endoscope, eyepiece attachment for prescription lens, teaching attachment, inflation bulb, measuring device for panendoscope, photographic equipment for physiologic function monitor, special lens instrument for endoscope, smoke removal tube, rechargeable battery box, pocket battery box, bite block for endoscope, and cleaning brush for endoscope.
H.1620	Urodynamics measurement system	1	A urodynamics measurement system is a device used to measure volume and pressure in the urinary bladder when it is filled through a catheter with carbon dioxide or water. The device controls the supply of carbon dioxide or water and may also record the electrical activity of the muscles associated with urination. The device system may include transducers, electronic signal conditioning and display equipment, a catheter withdrawal device to enable a urethral pressure profile to be obtained, and special catheters for urethral profilometry and electrodes for electromyography. This generic type of device includes the cystometric gas (carbon dioxide) device, the cystometric hydrualic device, and the electrical recording cystometer, but excludes any device that uses air to fill the bladder.
H.1725	Gastrointestinal motility monitoring system	2	A gastrointestinal motility monitoring system is a device used to measure peristalic activity or pressure in the stomach or esophagus by means of a probe with transducers that is introduced through the mouth into the gastrointestinal tract. The device may include signal conditioning, amplifying, and recording equipment. This generic type of device includes the esophageal motility monitor and tube, the gastrointestinal motility (electrical) system, and certain accessories, such as a pressure transducer, amplifier, and external recorder.

H.1735	Electrogastrography system	2	An electrogastrography system (EGG) is a device used to measure gastric myoelectrical activity as an aid in the diagnosis of gastric motility disorders. The device system includes the external recorder, amplifier, skin electrodes, strip chart, cables, analytical software, and other accessories.
H.1800	Urine flow or volume measuring system	1	A urine flow or volume measuring system is a device that measures directly or indirectly the volume or flow of urine from a patient, either during the course of normal urination or while the patient is catheterized. The device may include a drip chamber to reduce the risk of retrograde bacterial contamination of the bladder and a transducer and electrical signal conditioning and display equipment. This generic type of device includes the electrical urinometer, mechanical urinometer, nonelectric urinometer, disposable nonelectric urine flow rate measuring device, and uroflowmeter.
H.2050	Prostate lesion documentation system	2	A prostate lesion documentation system is a prescription device intended for use in producing an image of the prostate as an aid in documenting prostate abnormalities previously identified during a digital rectal examination. The device uses pressure sensors and image reconstruction software to produce a prostate image that highlights regional differences in intraprostatic tissue elasticity or stiffness. The device is limited to use as a documentation tool and is not intended for diagnostic purposes or for influencing any clinical decisions.
H.3350	Penile inflatable implant	3	A penile inflatable implant is a device that consists of two inflatable cylinders implanted in the penis, connected to a reservoir filled with radiopaque fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. When the cylinders are inflated, they provide rigidity to the penis. This device is used in the treatment of erectile impotence.
H.3630	Penile rigidity implant	2	A penile rigidity implant is a device that consists of a pair of semi-rigid rods implanted in the corpora cavernosa of the penis to provide rigidity. It is intended to be used in men diagnosed as having erectile dysfunction.
H.3750	Testicular prosthesis	3	A testicular prosthesis is an implanted device that consists of a solid or gel-filled silicone rubber prosthesis that is implanted surgically to resemble a testicle.
H.4020	Fiberoptic light ureteral catheter	2	A fiberoptic light ureteral catheter is a device that consists of a fiberoptic bundle that emits light throughout its length and is shaped so that it can be inserted into the ureter to enable the path of the ureter to be seen during lower abdominal or pelvic surgery.
H.4270	Colostomy rod	2	A colostomy rod is a device used during the loop colostomy procedure. A loop of colon is surgically brought out through the abdominal wall and the stiff colostomy rod is placed through the loop temporarily to keep the colon from slipping back through the surgical opening.

H.4300	Endoscopic electrosurgical unit and accessories	2	An endoscopic electrosurgical unit and accessories is a device used to perform electrosurgical procedures through an endoscope. This generic type of device includes the electrosurgical generator, patient plate, electric biopsy forceps, electrode, flexible snare, electrosurgical alarm system, electrosurgical power supply unit, electrical clamp, self-opening rigid snare, flexible suction coagulator electrode, patient return wristlet, contact jelly, adaptor to the cord for transurethral surgical instruments, the electric cord for transurethral surgical instruments, and the transurethral desiccator.
H.4370	Gastroenterology -urology evacuator	1,2	A gastroenterology-urology evacuator is a device used to remove debris and fluids during gastroenterological and urological procedures by drainage, aspiration, or irrigation. This generic type of device includes the fluid evacuator system, manually powered bladder evacuator, and the AC-powered vacuum pump. Classification: (1) Class 2 devices for the gastroenterology-urology evacuator when other than manually powered. ；(2) Class 1 devices for the gastroenterology-urology evacuator when manually powered.
H.4400	Hemorrhoidal ligator	2	A hemorrhoidal ligator is a device used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or band placed around the hemorrhoid.
H.4480	Electrohydraulic lithotriptor	2	An electrohydraulic lithotriptor is an AC-powered device used to fragment urinary bladder stones. It consists of a high voltage source connected by a cable to a bipolar electrode that is introduced into the urinary bladder through a cystoscope. The electrode is held against the stone in a water-filled bladder and repeated electrical discharges between the two poles of the electrode cause electrohydraulic shock waves which disintegrate the stone.
H.4500	Mechanical lithotriptor	2	A mechanical lithotriptor is a device with steel jaws that is inserted into the urinary bladder through the urethra to grasp and crush bladder stones.
H.4530	Gastroenterolgy-urology fiberoptic retractor	1	A gastroenterology-urology fiberoptic retractor is a device that consists of a mechanical retractor with a fiberoptic light system that is used to illuminate deep surgical sites.
H.4560	Ribdam	1	A ribdam is a device that consists of a broad strip of latex with supporting ribs used to drain surgical wounds where copious urine drainage is expected.
H.4590	Interlocking urethral sound	1	An interlocking urethral sound is a device that consists of two metal sounds (elongated instruments for exploring or sounding body cavities) with interlocking ends, such as with male and female threads or a rounded point and mating socket, used in the repair of a ruptured urethra. The device may include a protective cap to fit over the metal threads.
H.4620	Ureteral stent	2	A ureteral stent is a tube-like implanted device that is inserted into the ureter to provide ureteral rigidity and allow the passage of urine. The device may have finger-like protrusions or hooked ends to keep the tube in place. It is used in the treatment of ureteral injuries and ureteral obstruction.

H.4650	Water jet renal stone dislodger system	1	A water jet renal stone dislodger system is a device used to dislodge stones from renal calyces (recesses of the pelvis of the kidney) by means of a pressurized stream of water through a conduit. The device is used in the surgical removal of kidney stones.
H.4680	Ureteral stone dislodger	1	A ureteral stone dislodger is a device that consists of a bougie or a catheter with an expandable wire basket near the tip, a special flexible tip, or other special construction. It is inserted through a cystoscope and used to entrap and remove stones from the ureter. This generic type of device includes the metal basket and the flexible ureteral stone dislodger.
H.4730	Manual gastroenterolgoy-urology surgical instrument and accessories	1	A manual gastroenterology-urology surgical instrument and accessories is a device designed to be used for gastroenterological and urological surgical procedures. The device may be nonpowered, hand-held, or hand-manipulated. Manual gastroenterology-urology surgical instruments include the biopsy forceps cover, biopsy tray without biopsy instruments, line clamp, nonpowered rectal probe, nonelectrical clamp, colostomy spur-crushers, locking device for intestinal clamp, needle holder, gastro-urology hook, gastro-urology probe and director, nonself-retaining retractor, laparotomy rings, nonelectrical snare, rectal specula, bladder neck spreader, self-retaining retractor, and scoop.
H.4770	Urethrotome	2	A urethrotome is a device that is inserted into the urethra and used to cut urethral strictures and enlarge the urethra. It is a metal instrument equipped with a dorsal-fin cutting blade which can be elevated from its sheath. Some urethrotomes incorporate an optical channel for visual control.
H.4890	Urological table and accessories	1,2	A urological table and accessories is a device that consists of a table, stirrups, and belts used to support a patient in a suitable position for endoscopic procedures of the lower urinary tract. The table can be adjusted into position manually or electrically. Classification: (1)Class 2 devices for the electrically powered urological table and accessories.；(2)Class 1 devices for the manually powered table and accessories, and for stirrups for electrically powered table.
H.5010	Biliary catheter and accessories	2	A biliary catheter and accessories is a tubular flexible device used for temporary or prolonged drainage of the biliary tract, for splinting of the bile duct during healing, or for preventing stricture of the bile duct. This generic type of device may include a bile collecting bag that is attached to the biliary catheter by a connector and fastened to the patient with a strap.
H.5015	Pancreatic drainage stent	2	A pancreatic drainage stent is a prescription device that consists of a self-expanding, covered, metallic stent, intended for placement to facilitate transmural endoscopic drainage of pancreatic pseudocysts. This stent is intended to be removed upon confirmation of pseudocyst resolution. This device may also include a delivery system.

H.5020	External penile rigidity devices	2	External penile rigidity devices are devices intended to create or maintain sufficient penile rigidity for sexual intercourse. External penile rigidity devices include vacuum pumps, constriction rings, and penile splints which are mechanical, powered, or pneumatic devices.
H.5025	Vibrator for climax control of premature ejaculation	2	A vibrator for climax control of premature ejaculation is used for males who suffer from premature ejaculation. It is designed to increase the time between arousal and ejaculation using the stimulating vibratory effects of the device on the penis.
H.5030	Continent ileostomy catheter	1	A continent ileostomy catheter is a flexible tubular device used as a form during surgery for continent ileostomy and it provides drainage after surgery. Additionally, the device may be inserted periodically by the patient for routine care to empty the ileal pouch. This generic type of device includes the rectal catheter for continent ileostomy.
H.5090	Suprapubic urological catheter and accessories	1,2	A suprapubic urological catheter and accessories is a flexible tubular device that is inserted through the abdominal wall into the urinary bladder with the aid of a trocar and cannula. The device is used to pass fluids to and from the urinary tract. This generic type of device includes the suprapubic catheter and tube, Malecot catheter, catheter punch instrument, suprapubic drainage tube, and the suprapubic cannula and trocar. Classification: (1)Class 2；(2)Class 1 devices for the catheter punch instrument, nondisposable cannula and trocar, and gastro-urological trocar.
H.5130	Urological catheter and accessories	1,2	A urological catheter and accessories is a flexible tubular device that is inserted through the urethra and used to pass fluids to or from the urinary tract. This generic type of device includes radiopaque urological catheters, ureteral catheters, urethral catheters, coudecatheters, balloon retention type catheters, straight catheters, upper urinary tract catheters, double lumen female urethrographic catheters, disposable ureteral catheters, male urethrographic catheters, and urological catheter accessories including ureteral catheter stylets, ureteral catheter adapters, ureteral catheter holders, ureteral catheter stylets, ureteral catheterization trays, and the gastro-urological irrigation tray (for urological use). Classification: (1)Class 2；(2)Class 1 devices for the ureteral stylet (guidewire), stylet for gastrourological catheter, ureteral catheter adapter, ureteral catheter connector, and ureteral catheter holder.
H.5140	Urethral insert with pump for bladder drainage	2	A urethral insert with pump for bladder drainage is a catheter-like device with internal pump mechanism that is placed in the urethra. Under patient control the internal pump draws urine out of the bladder when voiding is desired, and blocks urine flow when continence is desired. The device is intended for use by women who cannot empty their bladder due to impaired detrusor contractility.
H.5160	Urological clamp for males	1	A urological clamp for males is a device used to close the urethra of a male to control urinary incontinence or to hold anesthetic or radiography contrast media in the urethra temporarily. It is an external clamp.

H.5210	Enema kit	1	An enema kit is a device intended to instill water or other fluids into the colon through a nozzle inserted into the rectum to promote evacuation of the contents of the lower colon. The device consists of a container for fluid connected to the nozzle either directly or via tubing. This device does not include the colonic irrigation system.
H.5220	Colonic irrigation system	2,3	A colonic irrigation system is a device intended to instill water into the colon through a nozzle inserted into the rectum to cleanse (evacuate) the contents of the lower colon. The system is designed to allow evacuation of the contents of the colon during the administration of the colonic irrigation. The device consists of a container for fluid connected to the nozzle via tubing and includes a system which enables the pressure, temperature, or flow of water through the nozzle to be controlled. The device may include a console-type toilet and necessary fittings to allow the device to be connected to water and sewer pipes. The device may use electrical power to heat the water. The device does not include the enema kit. Classification: (1)Class 2 devices intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations.；(2)Class 3 devices intended for other uses, including colon cleansing routinely for general well being.
H.5250	Urine collector and accessories	1,2	A urine collector and accessories is a device intended to collect urine. The device and accessories consist of tubing, a suitable receptacle, connectors, mechanical supports, and may include a means to prevent the backflow of urine or ascent of infection. The two kinds of urine collectors are: (1) A urine collector and accessories intended to be connected to an indwelling catheter, which includes the urinary drainage collection kit and the closed urine drainage system and drainage bag; and (2) A urine collector and accessories not intended to be connected to an indwelling catheter, which includes the corrugated rubber sheath, pediatric urine collector, leg bag for external use, urosheath type incontinence device, and the paste-on device for incontinence. Classification:(1) Class 2 for a urine collector and accessories intended to be connected to an indwelling catheter. ；(2) Class 1 for a urine collector and accessories not intended to be connected to an indwelling catheter.
H.5270	Implanted electrical urinary continence device	3	An implanted electrical urinary device is a device intended for treatment of urinary incontinence that consists of a receiver implanted in the abdomen with electrodes for pulsed-stimulation that are implanted either in the bladder wall or in the pelvic floor, and a battery-powered transmitter outside the body.
H.5280	Implanted mechanical/hydraulic urinary continence device	3	An implanted mechanical/hydraulic urinary continence device is a device used to treat urinary incontinence by the application of continuous or intermittent pressure to occlude the urethra. The totally implanted device may consist of a static pressure pad, or a system with a container of radiopaque fluid in the abdomen and a manual pump and valve under the skin surface that is connected by tubing to an adjustable pressure pad or to a cuff around the urethra. The fluid is pumped as needed from the container to inflate the pad or cuff to pass on the urethra.

H.5310	Nonimplanted, peripheral electrical continence device	2	A nonimplanted, peripheral electrical continence device is a device that consists of an electrode that is connected by an electrical cable to a battery-powered pulse source. The electrode is placed onto or inserted into the body at a peripheral location and used to stimulate the nerves associated with pelvic floor function to maintain urinary continence. When necessary, the electrode may be removed by the user.
H.5320	Nonimplanted electrical continence device.	2	A nonimplanted electrical continence device is a device that consists of a pair of electrodes on a plug or a pessary that are connected by an electrical cable to a powered pulse source. The plug or pessary is inserted into the rectum or into the vagina and used to stimulate the muscles of the pelvic floor to maintain urinary or fecal continence. When necessary, the plug or pessary may be removed by the user. This classification excludes an AC-powered nonimplanted electrical continence device and the powered vaginal muscle stimulator for therapeutic use (L.5940).
H.5365	Esophageal dilator	2	An esophageal dilator is a device that consists of a cylindrical instrument that may be hollow and weighted with mercury or a metal olive-shaped weight that slides on a guide, such as a string or wire and is used to dilate a stricture of the esophagus. This generic type of device includes esophageal or gastrointestinal bougies and the esophageal dilator (metal olive).
H.5450	Rectal dilator	1	A rectal dilator is a device designed to dilate the anal sphincter and canal when the size of the anal opening may interfere with its function or the passage of an examining instrument.
H.5470	Ureteral dilator	2	A ureteral dilator is a device that consists of a specially shaped catheter or bougie and is used to dilate the ureter at the place where a stone has become lodged or to dilate a ureteral stricture.
H.5520	Urethral dilator	1,2	A urethral dilator is a device that consists of a slender hollow or solid instrument made of metal, plastic, or other suitable material in a cylindrical form and in a range of sizes and flexibilities. The device may include a mechanism to expand the portion of the device in the urethra and indicate the degree of expansion on a dial. It is used to dilate the urethra. This generic type of device includes the mechanical urethral dilator, urological bougies, metal or plastic urethral sound, urethrometer, filiform, and filiform follower. Classification: (1)Class 2 ; (2)Class 1 for the urethrometer, urological bougie, filiform and filiform follower, and metal or plastic urethral sound.
H.5530	Implantable transprostatic tissue retractor system	2	An implantable transprostatic tissue retractor system is a prescription use device that consists of a delivery device and implant. The delivery device is inserted transurethrally and deploys the implant through the prostate. It is designed to increase prostatic urethral patency by providing prostate lobe tissue retraction while preserving the potential for future prostate procedures and is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia in men.

H.5540	Blood access device and accessories	1,2	A blood access device and accessories is a device intended to provide access to a patient's blood for hemodialysis or other chronic uses. When used in hemodialysis, it is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and provides access to a patient's blood for hemodialysis. The device includes implanted blood access devices, nonimplanted blood access devices, and accessories for both the implanted and nonimplanted blood access devices.(1) The implanted blood access device is a prescription device and consists of various flexible or rigid tubes, such as catheters, or cannulae, which are surgically implanted in appropriate blood vessels, may come through the skin, and are intended to remain in the body for 30 days or more. This generic type of device includes various catheters, shunts, and connectors specifically designed to provide access to blood. Examples include single and double lumen catheters with cuff(s), fully subcutaneous port-catheter systems, and A-V shunt cannulae (with vessel tips). The implanted blood access device may also contain coatings or additives which may provide additional functionality to the device. (2)The nonimplanted blood access device consists of various flexible or rigid tubes, such as catheters, cannulae or hollow needles, which are inserted into appropriate blood vessels or a vascular graft prosthesis, and are intended to remain in the body for less than 30 days. This generic type of device includes fistula needles, the single needle dialysis set (coaxial flow needle), and the single needle dialysis set (alternating flow needle).(3)Accessories common to either type include the shunt adaptor, cannula clamp, shunt connector, shunt stabilizer, vessel dilator, disconnect forceps, shunt guard, crimp plier, tube plier, crimp ring, joint ring, fistula adaptor, and declotting tray (including contents). Classification:(1)Class 2 (special controls) for the implanted blood access device. ;(2)Class 2 for the nonimplanted blood access device. ;(3) Class 2 for accessories for both the implanted and the nonimplanted blood access devices not listed in paragraph.(4)of this section.;(4)Class 1 for the cannula clamp, disconnect forceps, crimp plier, tube plier, crimp ring, and joint ring, accessories for both the implanted and nonimplanted blood access device.
H.5600	Sorbent regenerated dialysate delivery system for hemodialysis	2	A sorbent regenerated dialysate delivery system for hemodialysis is a device that is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that consists of a sorbent cartridge and the means to circulate dialysate through this cartridge and the dialysate compartment of the dialyzer. The device is used with the extracorporeal blood system and the dialyzer of the hemodialysis system and accessories (876.5820). The device includes the means to maintain the temperature, conductivity, electrolyte balance, flow rate and pressure of the dialysate, and alarms to indicate abnormal dialysate conditions. The sorbent cartridge may include absorbent, ion exchange and catalytic materials.

H.5630	Peritoneal dialysis system and accessories	2	(1)A peritoneal dialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that consists of a peritoneal access device, an administration set for peritoneal dialysis, a source of dialysate, and, in some cases, a water purification mechanism. After the dialysate is instilled into the patient's peritoneal cavity, it is allowed to dwell there so that undesi- rable substances from the patient's blood pass through the lining membrane of the peritoneal cavity into this dialysate. These substances are then removed when the dialysate is drained from the patient. The peritoneal dialysis system may regulate and monitor the dialysate temperature, volume, and delivery rate together with the time course of each cycle of filling, dwell time, and draining of the peritoneal cavity or manual controls may be used. This generic device includes the semiautomatic and the automatic perito- neal delivery system.(2)The peritoneal access device is a flexible tube that is implanted through the abdominal wall into the peritoneal cavity and that may have attached cuffs to provide anchoring and a skin seal. The device is either a single use peritioneal catheter, intended to remain in the peritoneal cavity for less than 30 days, or a long term peritoneal catheter. Accessories include stylets and trocars to aid in the insertion of the catheter and an obturator to maintain the patency of the surgical fistula in the abdominal wall between treatments.(3)The disposable administration set for peritoneal dialysis consists of tubing, an optional reservoir bag, and appropriate connectors. It may include a peritoneal dialysate filter to trap and remove contaminating particles.(4)The source of dialysate may be sterile prepackaged dialysate (for semiautomatic peritoneal dialysate delivery systems or "cycler systems") or dialysate prepared from dialysate concentrate and sterile purified water (for automatic peritoneal dialysate delivery systems or "reverse osmosis" systems). Prepackaged dialysate intended for use with either of the peritoneal dialysate delivery systems is regulated by FDA as a drug.
H.5665	Water purification system for hemodialysis	2	A water purification system for hemodialysis is a device that is intended for use with a hemodialysis system and that is intended to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate. This generic type of device may include a water softener, sediment filter, carbon filter, and water distillation system.

H.5820	Hemodialysis system and accessories	1,2	A hemodialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer. (1) The extracorporeal blood system and accessories consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis (876.5540) to the blood compartment of the dialyzer and back to the patient. (2) The conventional dialyzer allows a transfer of water and solutes between the blood and the dialysate through the semipermeable membrane. The semipermeable membrane of the conventional dialyzer has a sufficiently low permeability to water that an ultrafiltration controller is not required to prevent excessive loss of water from the patient's blood. This conventional dialyzer does not include hemodialyzers with the disposable inserts (Kiil type) (876.5830) or dialyzers of high permeability (876.5860). (3) The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the dialysate and circulates dialysate through the dialysate compartment of the dialyzer. The dialysate delivery system includes the dialysate concentrate for hemodialysis (liquid or powder) and alarms to indicate abnormal dialysate conditions. This dialysate delivery system does not include the sorbent regenerated dialysate delivery system for hemodialysis (876.5600), the dialysate delivery system of the peritoneal dialysis system and accessories (876.5630), or the controlled dialysate delivery system of the high permeability hemodialysis system 876.5860). (4) Remote accessories to the hemodialysis system include the unpowered dialysis chair without a scale, the powered dialysis chair without a scale, the dialyzer holder set, dialysis tie gun and ties, and hemodialysis start/stop tray.

H.5830	(kiil type)(Hemodialyzer with disposable insert (kiil type)	2	Classification: (1)Class 2 for hemodialysis systems and all accessories directly associated with the extracorporeal blood system and the dialysate delivery system.；(2)Class 1 for other accessories of the hemodialysis system remote from the extracorporeal blood system and the dialysate delivery system, such as the unpowered dialysis chair, hemodialysis start/stop tray, dialyzer holder set, and dialysis tie gun and ties.
H.5860	High permeability hemodialysis system	2	A high permeability hemodialysis system is a device intended for use as an artificial kidney system for the treatment of patients with renal failure, fluid overload, or toxemic conditions by performing such therapies as hemodialysis, hemofiltration, hemoconcentration, and hemodiafiltration. Using a hemodialyzer with a semipermeable membrane that is more permeable to water than the semipermeable membrane of the conventional hemodialysis system (876.5820), the high permeability hemodialysis system removes toxins or excess fluid from the patient's blood using the principles of convection (via a high ultrafiltration rate) and/or diffusion (via a concentration gradient in dialysate). During treatment, blood is circulated from the patient through the hemodialyzer's blood compartment, while the dialysate solution flows countercurrent through the dialysate compartment. In this process, toxins and/or fluid are transferred across the membrane from the blood to the dialysate compartment. The hemodialysis delivery machine controls and monitors the parameters related to this processing, including the rate at which blood and dialysate are pumped through the system, and the rate at which fluid is removed from the patient. The high permeability hemodialysis system consists of the following devices: (1) The hemodialyzer consists of a semipermeable membrane with an in vitro ultrafiltration coefficient (Kuf) greater than 8 milliliters per hour per conventional millimeter of mercury, as measured with bovine or expired human blood, and is used with either an automated ultrafiltration controller or anther method of ultrafiltration control to prevent fluid imbalance. (2) The hemodialysis delivery machine is similar to the extracorporeal blood system and dialysate delivery system of the hemodialysis system and accessories (876.5820), with the addition of an ultrafiltration controller and mechanisms that monitor and/or control such parameters as fluid balance, dialysate composition, and patient treatment parameters (e.g., blood pressure, hematocrit, urea, etc.). (3) The high permeability hemodialysis system accessories include, but are not limited to, tubing lines and various treatment related monitors (e.g., dialysate pH, blood pressure, hematocrit, and blood recirculation monitors).

H.5870	Sorbent hemoperfusion system	3	A sorbent hemoperfusion system is a device that consists of an extracorporeal blood system similar to that identified in the hemodialysis system and accessories (876.5820) and a container filled with adsorbent material that removes a wide range of substances, both toxic and normal, from blood flowing through it. The adsorbent materials are usually activated-carbon or resins which may be coated or immobilized to prevent fine particles entering the patient's blood. The generic type of device may include lines and filters specifically designed to connect the device to the extracorporeal blood system. The device is used in the treatment of poisoning, drug overdose, hepatic coma, or metabolic disturbances.
H.5880	Isolated kidney perfusion and transport system and accessories	2	An isolated kidney perfusion and transport system and accesssories is a device that is used to support a donated or a cadaver kidney and to maintain the organ in a near-normal physiologic state until it is transplanted into a recipient patient. This generic type of device may include tubing, catheters, connectors, an ice storage or freezing container with or without bag or preservatives, pulsatile or nonpulsatile hypothermic isolated organ perfusion apparatus with or without oxygenator, and disposable perfusion set. The item includes the preservation solutions for organs.
H.5885	Tissue culture media for human ex vivo tissue and cell culture processing applications	2	Tissue culture media for human ex vivo tissue and cell culture processing applications consist of cell and tissue culture media and components that are composed of chemically defined components (e.g., amino acids, vitamins, inorganic salts) that are essential for the ex vivo development, survival, and maintenance of tissues and cells of human origin. The solutions are indicated for use in human ex vivo tissue and cell culture processing applications.
H.5895	Ostomy irrigator	2	An ostomy irrigator is a device that consists of a container for fluid, tubing with a cone-shaped tip or a soft and flexible catheter with a retention shield and that is used to wash out the colon through a colostomy, a surgically created opening of the colon on the surface of the body.
H.5930	Rectal control system	2	A rectal control system is a prescription device intended to treat fecal incontinence by controlling the size of the rectal lumen. The device is inserted in the vagina and includes a portion that expands to reduce the rectal lumen to prevent stool leakage and retracts to allow normal passage of stool. The device includes an external regulator to control the state of expansion.
H.5900	Ostomy pouch and accessories	1	An ostomy pouch and accessories is a device that consists of a bag that is attached to the patient's skin by an adhesive material and that is intended for use as a receptacle for collection of fecal material or urine following an ileostomy, colostomy, or ureterostomy (a surgically created opening of the small intestine, large intestine, or the ureter on the surface of the body). This generic type of device and its accessories includes the ostomy pouch, ostomy adhesive, the disposable colostomy appliance, ostomy collector, colostomy pouch, urinary ileostomy bag, urine collecting ureterostomy bag, ostomy drainage bag with adhesive, stomal bag, ostomy protector, and the ostomy size selector, but excludes ostomy pouches which incorporate arsenic-containing compounds.

H.5955	Peritoneo-venous shunt	2	A peritoneo-venous shunt is an implanted device that consists of a catheter and a pressure activated one-way valve. The catheter is implanted with one end in the peritoneal cavity and the other in a large vein. This device enables ascitic fluid in the peritoneal cavity to flow into the venous system for the treatment of intractable ascites.
H.5970	Hernia support	1	A hernia support is a device, usually made of elastic, canvas, leather, or metal, that is intended to be placed over a hernial opening (a weakness in the abdominal wall) to prevent protrusion of the abdominal contents. This generic type of device includes the umbilical truss.
H.5980	Gastrointestinal tube and accessories	1,2	A gastrointestinal tube and accessories is a device that consists of flexible or semi-rigid tubing used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract. This device may incorporate an integral inflatable balloon for retention or hemostasis. This generic type of device includes the hemostatic bag, irrigation and aspiration catheter (gastric, colonic, etc.), rectal catheter, sterile infant gavage set, gastrointestinal string and tubes to locate internal bleeding, double lumen tube for intestinal decompression or intubation, feeding tube, gastroenterostomy tube, Levine tube, nasogastric tube, single lumen tube with mercury weight balloon for intestinal intubation or decompression, and gastro-urological irrigation tray (for gastrological use). Classification: (1)Class 2；(2)Class 1 for the dissolvable nasogastric feed tube guide for the nasogastric tube.
H.5990	Extracorporeal shock wave lithotripter	2	An extracorporeal shock wave lithotripter is a device that focuses ultrasonic shock waves into the body to noninvasively fragment urinary calculi within the kidney or ureter. The primary components of the device are a shock wave generator, high voltage generator, control console, imaging/localization system, and patient table. Prior to treatment, the urinary stone is targeted using either an integral or stand-alone localization/imaging system. Shock waves are typically generated using electrostatic spark discharge (spark gap), electromagnetically repelled membranes, or piezoelectric crystal arrays, and focused onto the stone with either a specially designed reflector, dish, or acoustic lens. The shock waves are created under water within the shock wave generator, and are transferred to the patient's body using an appropriate acoustic interface. After the stone has been fragmented by the focused shock waves, the fragments pass out of the body with the patient's urine.
H.9999	Others(Gastroenterology and Urology Devices)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.
I.0001	High density electrical current subcutaneous wrinkle reduction device	2	A device with high density electrical current for subcutaneous wrinkle reduction is a device applying an electrical current to electrodes on a patient's skin up to subdermal or muscle layers for reducing body wrinkles and connective tissue swelling by physical action. This device applies high density electrical current to stimulate collagen and elastin production by heating tissues in the deep layers of the skin.

I.0002	Collagen implant	3	A collagen implant is a device primarily composed of collagen to correct or be implanted in facial or other body surface where weakness exists.
I.0003	Ultrasonic surgical instrument	2	An ultrasonic surgical instrument is a surgical device for soft tissue ablation. This device contains ultrasound generator and accessories including control console, ultrasound applicator(s), foot switch, and waste collector.
I.0004	Alcohol pad	2	An alcohol pad is a non-absorbable piece of cotton containing alcohol used for, e.g., skin cleaning, disinfection and medical purposes.
I.0005	Providone-Iodine pad	2	A Providone-Iodine pad is a non-absorbable piece of cotton containing Providone-Iodine used for, e.g., skin cleaning, disinfection and medical purposes.
I.0006	Medical protective clothing	2	Medical protective clothing are devices that are intended to be worn by medical personnel in medical environments. These devices protect medical personnel from cross-infection. These devices are to protect whole or part of the body from the environments. Surgical gowns are not included in this identification. Classification: Class 2.
I.0007	Hyaluronic Acid Implants	3	Hyaluronic acid implants are hyaluronic acid substances used to modify or filled into surface defects on the face or other body positions.
I.0008	Transcutaneous skin stimulator	2	A transcutaneous skin stimulator applies energy (e.g., electrical current, optical energy or ultrasound energy) on a patient's skin up to dermal or subdermal layers to modify skin appearance (e.g., skin tightening, toning, lifting or reducing wrinkles) or to stimulate collagen or cell production.
I.0009	High Intensity Focused Ultrasound (HIFU) Ablation System	3	An high intensity focused ultrasound (HIFU) ablation system is intended to use HIFU to ablate soft tissue or specific cell tissue. The system needs to be used with medical imaging systems (e.g., MR imaging systems) used for guiding the procedure.
I.0010	Adhesion Barrier Material	3	Adhesion barrier material, which can be in the form of colloid or film, as a temporary physical barrier to separate tissues to reduce fibrosis and reduce the formation of adhesions. It can be used in general surgical sites, not in other specialty areas or the one that already has adhesion barrier materials in related categories.
I.4165	Wound autofluorescence imaging device	2	A wound autofluorescence imaging device is a tool to view autofluorescence images from skin wounds that are exposed to an excitation light. The device is not intended to provide quantitative or diagnostic information.
I.4371	Irrigating wound retractor device	2	An irrigating wound retractor device is a prescription device intended to be used by a surgeon to retract the surgical incision, to provide access to the surgical wound, to protect and irrigate the surgical wound, and to serve as a conduit for removal of fluid from the surgical wound.
I.4685	Extracorporeal shock wave device	2	An extracorporeal shock wave device for treatment of chronic wounds is a prescription device that focuses acoustic shock waves onto the dermal tissue. The shock waves are generated inside the device and transferred to the body using an acoustic interface.

I.4815	Magnetic surgical instrument system	2	A magnetic surgical instrument system is a prescription device used in laparoscopic surgical procedures consisting of several components, such as surgical instruments, and a magnetic controller. The magnetic controller is provided separately from the surgical instrument and is used outside the patient. The external magnetic controller is magnetically coupled with the internal surgical instrument(s) at the surgical site to grasp, hold, retract, mobilize, or manipulate soft tissue and organs.
I.1800	Speculum and accessories	1	A speculum is a device intended to be inserted into a body cavity to aid observation. It is either nonilluminated or illuminated and may have various accessories.
I.3250	External facial fracture fixation appliance	1	An external facial fracture fixation appliance is a metal apparatus intended to be used during surgical reconstruction and repair to immobilize maxillofacial bone fragments in their proper facial relationship.
I.3300	Surgical mesh	2	Surgical mesh is a metallic or polymeric screen intended to be implanted to reinforce soft tissue or bone where weakness exists. Examples of surgical mesh are metallic and polymeric mesh for hernia repair, and acetabular and cement restrictor mesh used during orthopedic surgery.
I.3500	Polytetrafluoroethylene with carbon fibers composite implant material	2	A polytetrafluoroethylene with carbon fibers composite implant material is a porous device material intended to be implanted during surgery of the chin, jaw, nose, or bones or tissue near the eye or ear. The device material serves as a space-occupying substance and is shaped and formed by the surgeon to conform to the patient's need.
I.3530	Silicone inflatable breast prosthesis	3	A silicone inflatable breast prosthesis is a silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, that is inflated to the desired size with sterile isotonic saline before or after implantation. The device is intended to be implanted to augment or reconstruct the female breast.

I.3540	Silicone gel-filled breast prosthesis	3	(1)Single-lumen silicone gel-filled breast prosthesis. A single-lumen silicone gel-filled breast prosthesis is a silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane. The shell either contains a fixed amount cross-linked polymerized silicone gel, filler, and stabilizers or is filled to the desired size with injectable silicone gel at time of implantation. The device is intended to be implanted to augment or reconstruct the female breast.(2)Double-lumen silicone gel-filled breast prosthesis. A double lumen silicone gel-filled breast prosthesis is a silicone rubber inner shell and a silicone rubber outer shell, both shells made of polysiloxane(s), such as polydi- methylsiloxane and polydiphenylsiloxane. The inner shell contains fixed amounts of cross-linked polymerized silicone gel, fillers, and stabilizers. The outer shell is inflated to the desired size with sterile isotonic saline before or after implantation. The device is intended to be implanted to augment or reconstruct the female breast.(3)Polyurethane covered silicone gel-filled breast prosthesis. A polyurethane covered silicone gel-filled breast prosthesis is an inner silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, with an outer silicone adhesive layer and an outer covering of polyurethane; contained within the inner shell is a fixed amount of cross-linked polymerized silicone gel, fillers, and stabilizers and an inert support structure compartmentalizing the silicone gel. The device is intended to be implanted to augment or reconstruct the female breast.
I.3550	Chin prosthesis	2	A chin prosthesis is a silicone rubber solid device intended to be implanted to augment or reconstruct the chin.
I.3590	Ear prosthesis	2	An ear prosthesis is a silicone rubber solid device intended to be implanted to reconstruct the external ear.
I.3610	Esophageal prosthesis	2	An esophageal prosthesis is a rigid, flexible, or expandable tubular device made of a plastic, metal, or polymeric material that is intended to be implanted to restore the structure and/or function of the esophagus. The metal esophageal prosthesis may be uncovered or covered with a polymeric material. This device may also include a device delivery system.
I.3680	Nose prosthesis	2	A nose prosthesis is a silicone rubber solid device intended to be implanted to augment or reconstruct the nasal dorsum.
I.3720	Tracheal prosthesis	2	The tracheal prosthesis is a rigid, flexible, or expandable tubular device made of a silicone, metal, or polymeric material that is intended to be implanted to restore the structure and/or function of the trachea or trachealbronchial tree. It may be unbranched or contain one or two branches. The metal tracheal prosthesis may be uncovered or covered with a polymeric material. This device may also include a device delivery system.
I.3800	External aesthetic restoration prosthesis	1	An external aesthetic restoration prosthesis is a device intended to be used to construct an external artificial body structure, such as an ear, breast, or nose. Usually the device is made of silicone rubber and it may be fastened to the body with an external prosthesis adhesive. The device is not intended to be implanted.
I.3900	Inflatable extremity splint	1	An inflatable extremity splint is a device intended to be inflated to immobilize a limb or an extremity.

I.3910	Noninflatable extremity splint	1	A noninflatable extremity splint is a device intended to immobilize a limb or an extremity. It is not inflatable.
I.3925	Plastic surgery kit and accessories	1	A plastic surgery kit and accessories is a device intended to be used to reconstruct maxillofacial deficiencies. The kit contains surgical instruments and materials used to make maxillofacial impressions before molding an external prosthesis.
I.4010	Tissue adhesive	2,3	(a)Tissue adhesive for the topical approximation of skin --(1)Identification: A tissue adhesive for the topical approximation of skin is a device intended for topical closure of surgical incisions, including laparoscopic incisions, and simple traumatic lacerations that have easily approximated skin edges. Tissue adhesives for the topical approximation of skin may be used in conjunction with, but not in place of, deep dermal stitches. (2)Classification:Class 2. (b)Tissue adhesive for non-topical use --(1)Identification: A tissue adhesive for non-topical use, including adhesives intended for use in the embolization of brain arteriovenous malformation or for use in ophthalmic surgery, is a device used for adhesion of internal tissues and vessels. (2)Classification:Class 3.
I.4011	Tissue adhesive with adjunct wound closure device for topical approximation of skin	2	A tissue adhesive with adjunct wound closure device intended for the topical approximation of skin is a device indicated for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. It may be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of wound during application of the liquid adhesive. Classification: Class 2.
I.4014	Nonresorbable gauze/sponge for external use	1,2	A nonresorbable gauze/sponge for external use is a sterile or nonsterile device intended for medical purposes, such as to be placed directly on a patient's wound to absorb exudate. It consists of a strip, piece, or pad made from open woven or nonwoven mesh cotton cellulose or a simple chemical derivative of cellulose. This classification does not include a nonresorbable gauze/sponge for external use that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources. Classification: Class 2.
I.4015	Wound dressing with poly (diallyl dimethyl ammonium chloride) (pDADMAC) additive	2	A wound dressing with pDADMAC additive is intended for use as a primary dressing for exuding wounds, 1st and 2d degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing.

I.4018	Hydrophilic wound dressing	1,2	A hydrophilic wound dressing is a sterile or non-sterile device intended to cover a wound and to absorb exudate. It consists of nonresorbable materials with hydrophilic properties that are capable of absorbing exudate (e.g., cotton, cotton derivatives, alginates, dextran, and rayon). Classification: (1)Class 2 devices that are intended for patients with class 3 burning wound, free sewing(replacing surgical suture), contain added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.；(2)Class 1 other devices.
I.4020	Occlusive wound/burn dressing	1,2	An occlusive wound dressing is a nonresorbable, sterile or non-sterile device intended to cover a wound, to provide or support a moist wound environment, and to allow the exchange of gases such as oxygen and water vapor through the device. It consists of a piece of synthetic polymeric material, such as polyurethane, with or without an adhesive backing.z Classification: (1)Class 2 devices that are intended for patients with class 3 burning wound, free sewing(replacing surgical suture), contain added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.；(2)Class 1 other devices.
I.4022	Hydrogel wound dressing and burn dressing	1,2	A hydrogel wound dressing is a sterile or non-sterile device intended to cover a wound, to absorb wound exudate, to control bleeding or fluid loss, and to protect against abrasion, friction, desiccation, and contamination. It consists of a nonresorbable matrix made of hydrophilic polymers or other material in combination with water (at least 50 percent) and capable of absorbing exudate. Classification: (1)Class 2 devices that are intended for patients with class 3 burning wound, free sewing(replacing surgical suture), contain added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.；(2)Class 1 other devices.
I.4025	Silicone scar management product	1	Silicone scar management product is intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars.
I.4040	Medical apparel	1,2	Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded. Classification: (1)Class 2 devices intended for surgical proocedure including surgical gowns and surgical masks. (2)Class 1 other devices. Medical masks are required to meet requirements from the national standard CNS 14774(T5017) or the others equivalent international standards. Masks which are claimed/labelled as N95 should meet D2 class (or higher) performance requirements from the national standard CNS 14755(Z2125).

I.4100	Organ bag	1	An organ bag is a device that is a flexible plastic bag intended to be used as a temporary receptacle for an organ during surgical procedures to prevent moisture loss.
I.4160	Surgical camera and accessories	1	A surgical camera and accessories is a device intended to be used to record operative procedures.
I.4200	Introduction/drainage catheter and accessories	1	An introduction/drainage catheter is a device that is a flexible single or multilumen tube intended to be used to introduce nondrug fluids into body cavities other than blood vessels, drain fluids from body cavities, or evaluate certain physiologic conditions. Examples include irrigation and drainage catheters, pediatric catheters, peritoneal catheters (including dialysis), and other general surgical catheters. An introduction/drainage catheter accessory is intended to aid in the manipulation of or insertion of the device into the body. Examples of accessories include adaptors, connectors, and catheter needles.
I.4300	Implantable clip	2	An implantable clip is a clip-like device intended to connect internal tissues to aid healing. It is not absorbable.
I.4320	Removable skin clip	1	A removable skin clip is a clip-like device intended to connect skin tissues temporarily to aid healing. It is not absorbable.
I.4340	Contact cooling system	2	A contact cooling system is a device that is a combination of a cooling pad associated with a vacuum or mechanical massager intended for the disruption of adipocyte cells intended for non-invasive use. Classification. Class II
I.4350	Cryosurgical unit and accessories	2	(1)Cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories. A cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures by applying extreme cold. (2)Cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories. A cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures, including urological applications, by applying extreme cold. (3)Cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator and accessories. A cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator and accessories is a device intended to destroy tissue during surgical procedures by applying extreme cold. The device is intended to treat disease conditions such as tumors, skin cancers, acne scars, or hemangiomas (benign tumors consisting of newly formed blood vessels) and various benign or malignant gynecological conditions affecting vulvar, vaginal, or cervical tissue. The device is not intended for urological applications.
I.4360	Scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia	2	A scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia is a prescription device intended to reduce the frequency and severity of alopecia during chemotherapy in which alopecia-inducing chemotherapeutic agents are used.

I.4370	Surgical drape and drape accessories	1,2	(a) A surgical drape and drape accessories is a device made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The device includes a plastic wound protector that may adhere to the skin around a surgical incision or be placed in a wound to cover its exposed edges, and a latex drape with a self-retaining finger cot that is intended to allow repeated insertion of the surgeon's finger into the rectum during performance of a transurethral prostatectomy. (b) Classification: (1) Class 2. (2) Class 1 for drape and cover intended for medical device covering.
I.4380	Drape adhesive	1	A drape adhesive is a device intended to be placed on the skin to attach a surgical drape.
I.4400	Electrosurgical cutting and coagulation device and accessories	2	An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current.
I.4410	Low energy ultrasound wound cleaner	2	A low energy ultrasound wound cleaner is a device that uses ultrasound energy to vaporize a solution and generate a mist that is used for the cleaning and maintenance debridement of wounds. Low levels of ultrasound energy may be carried to the wound by the saline mist.
I.4440	Eye pad	1	An eye pad is a device that consists of a pad made of various materials, such as gauze and cotton, intended for use as a bandage over the eye for protection or absorption of secretions.
I.4450	Nonabsorbable gauze for internal use	1	Nonabsorbable gauze for internal use is a device made of an open mesh fabric intended to be used inside the body or a surgical incision or applied to internal organs or structures, to control bleeding, absorb fluid, or protect organs or structures from abrasion, drying, or contamination. The device is woven from material made of not less than 50 percent by mass cotton, cellulose, or a simple chemical derivative of cellulose, and contains x-ray detectable elements.
I.4460	Surgeon's glove.	1,2	A surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded. A surgeon's glove containing biodegradable powders which complies with U.S.P. (for example corn powders) is class 2 device.Non-clinical performance data of the barrier property (water leak) and tensile strength should comply with ISO 10282, ASTM D 3577, EN 455 or equivalent standards.A non-powdered (powder free) surgeon's glove should comply with EN ISO 21171, ASTM D 6124 or equivalent standards. The amount of residual powders on a glove should not exceed 2.0 mg.
I.4470	Surgeon's gloving cream	1,2	Surgeon's gloving cream is an ointment intended to be used to lubricate the user's hand before putting on a surgeon's glove.

I.4480	Absorbable powder for lubricating a surgeon's glove	3	Absorbable powder for lubricating a surgeon's glove is a powder made from corn starch that meets the specifications for absorbable powder in the United States Pharmacopeia (U.S.P.) and that is intended to be used to lubricate the surgeon's hand before putting on a surgeon's glove. The device is absorbable through biological degradation.
I.4490	Absorbable hemostatic agent and dressing	3	An absorbable hemostatic agent or dressing is a device intended to produce hemostasis by accelerating the clotting process of blood. It is absorbable.
I.4493	Absorbable poly(glycolide/L-lactide) surgical suture	2	An absorbable poly(glycolide/l-lactide) surgical suture (PGL suture) is an absorbable sterile, flexible strand as prepared and synthesized from homopolymers of glycolide and copolymers made from 90 percent glycolide and 10 percentl-lactide, and is indicated for use in soft tissue approximation. A PGL suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. "Monograph for Absorbable Surgical Sutures;" it may be monofilament or multifilament (braided) in form; it may be uncoated or coated; and it may be undyed or dyed with an FDA-approved color additive. Also, the suture may be provided with or without a standard needle attached.
I.4494	Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology	2	An absorbable poly(hydroxybutyrate) surgical suture is an absorbable surgical suture made of material isolated from prokaryotic cells produced by recombinant deoxyribonucleic acid (DNA) technology. The device is intended for use in general soft tissue approximation and ligation.
I.4495	Stainless steel suture	2	A stainless steel suture is a needled or unneedled nonabsorbable surgical suture composed of 316L stainless steel, in USP sizes 12-0 through 10, or a substantially equivalent stainless steel suture, intended for use in abdominal wound closure, intestinal anastomosis, hernia repair, and sternal closure.
I.4520	Polytetrafluoroethylene injectable	3	Polytetrafluoroethylene injectable is an injectable paste prosthetic device composed of polytetrafluoroethylene intended to be used to augment or reconstruct a vocal cord.
I.4580	Surgical lamp	2	A surgical lamp (including a fixture) is a device intended to be used to provide visible illumination of the surgical field or the patient.
I.4590	Focused ultrasound stimulator system	2	A Focused Ultrasound Stimulator System is a device using focused ultrasound to produce localized, mechanical motion within tissues and cells for the purpose of producing either localized heating for tissue coagulation or for mechanical cellular membrane disruption intended for noninvasive use. Classification. Class II
I.4630	Ultraviolet lamp for dermatologic disorders	2	An ultraviolet lamp for dermatologic disorders is a device (including a fixture) intended to provide ultraviolet radiation of the body to photoactivate a drug in the treatment of a dermatologic disorder if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug.

I.4650	Aorto-saphenous vein ostia marker	2	An Aorto-saphenous vein ostia marker is used as a landmark to identify the anastomosis site of the vein utilizing fluorscopy. The marker is surgically attached to a anastomosis sites of the vein graft.
I.4660	Skin marker	1	A skin marker is a pen-like device intended to be used to write on the patient's skin, e.g., to outline surgical incision sites or mark anatomical sites for accurate blood pressure measurement.
I.4670	Internal tissue marker	2	An internal tissue marker is a prescription use device that is intended for use prior to or during general surgical procedures to demarcate selected sites on internal tissues.
I.4680	Nonpowered,single patient,portable suction apparatus	1	A nonpowered, single patient, portable suction apparatus is a device that consists of a manually operated plastic, disposable evacuation system intended to provide a vacuum for suction drainage of surgical wounds.
I.4683	Non-Powered suction apparatus device intended for negative pressure wound therapy	2	A non-powered suction apparatus device intended for negative pressure wound therapy is a device that is indicated for wound management via application of negative pressure to the wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. It is further indicated for management of wounds, burns, flaps, and grafts. Classification. Class II
I.4700	Surgical microscope and accessories	1	A surgical microscope and accessories is an AC-powered device intended for use during surgery to provide a magnified view of the surgical field.
I.4730	Surgical skin degreaser or adhesive tape solvent	1	A surgical skin degreaser or an adhesive tape solvent is a device that consists of a liquid such as 1,1,2-trichloro-1,2,2-trifluoroethane; 1,1,1-trichloroethane; and 1,1,1-trichloroethane with mineral spirits intended to be used to dissolve surface skin oil or adhesive tape.
I.4750	Implantable staple	2	An implantable staple is a staple-like device intended to connect internal tissues to aid healing. It is not absorbable.
I.4760	Removable skin staple	1	A removable skin staple is a staple-like device intended to connect external tissues temporarily to aid healing. It is not absorbable.
I.4780	Powered suction pump	2	A powered suction pump is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter.

I.4800	Manual surgical instrument for general use	1	A manual surgical instrument for general use is a nonpowered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, blood lancet, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, stapler, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892.
I.4810	Laser surgical instrument for use in general and plastic surgery and in dermatology	2	A laser device for use in general surgery, plastic surgery and dermatology is a laser device intended to cut, destroy, or remove tissue by light energy.
I.4820	Surgical instrument motors and accessories/attachments	1	Surgical instrument motors and accessories are AC-powered, battery-powered, or air-powered devices intended for use during surgical procedures to provide power to operate various accessories or attachments to cut hard tissue or bone and soft tissue. Accessories or attachments may include a bur, chisel (osteotome), dermabrasion brush, dermatome, drill bit, hammerhead, pin driver, and saw blade.
I.4830	Absorbable surgical gut suture	2	An absorbable surgical gut suture, both plain and chromic, is an absorbable, sterile, flexible thread prepared from either the serosal connective tissue layer of beef (bovine) or the submucosal fibrous tissue of sheep (ovine) intestine, and is intended for use in soft tissue approximation.
I.4840	Absorbable polydioxanone surgical suture	2	An absorbable polydioxanone surgical suture is an absorbable, flexible, sterile, monofilament thread prepared from polyester polymer poly (p-dioxanone) and is intended for use in soft tissue approximation, including pediatric cardiovascular tissue where growth is expected to occur, and ophthalmic surgery. It may be coated or uncoated, undyed or dyed, and with or without a standard needle attached.
I.4930	Suture retention device	1	A suture retention device is a device, such as a retention bridge, a surgical button, or a suture bolster, intended to aid wound healing by distributing suture tension over a larger area in the patient.
I.4950	Manual operating table and accessories and manual operating chair and accessories	1	A manual operating table and accessories and a manual operating chair and accessories are nonpowered devices, usually with movable components, intended to be used to support a patient during diagnostic examinations or surgical procedures.

I.4960	Operating tables and accessories and operating chairs and accessories	1	Operating tables and accessories and operating chairs and accessories are AC-powered or air-powered devices, usually with movable components, intended for use during diagnostic examinations or surgical procedures to support and position a patient.
I.5000	Nonabsorbable poly(ethylene terephthalate)surgical suture	2	Nonabsorbable poly(ethylene terephthalate) surgical suture is a multifilament, nonabsorbable, sterile, flexible thread prepared from fibers of high molecular weight, long-chain, linear polyesters having recurrent aromatic rings as an integral component and is indicated for use in soft tissue approximation. The poly(ethylene terephthalate) surgical suture meets U.S.P. requirements as described in the U.S.P. Monograph for Nonabsorbable Surgical Sutures; it may be provided uncoated or coated; and it may be undyed or dyed with an appropriate FDA listed color additive. Also, the suture may be provided with or without a standard needle attached.
I.5010	Nonabsorbable polypropylene surgical suture	2	Nonabsorbable polypropylene surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from long-chain polyolefin polymer known as polypropylene and is indicated for use in soft tissue approximation. The polypropylene surgical suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. Monograph for Nonabsorbable Surgical Sutures; it may be undyed or dyed with an FDA approved color additive; and the suture may be provided with or without a standard needle attached.
I.5020	Nonabsorbable polyamide surgical suture	2	Nonabsorbable polyamide surgical suture is a nonabsorbable, sterile, flexible thread prepared from long-chain aliphatic polymers Nylon 6 and Nylon 6,6 and is indicated for use in soft tissue approximation. The polyamide surgical suture meets United States Pharmacopeia (U.S.P.) requirements as described in the U.S.P. monograph for nonabsorbable surgical sutures; it may be monofilament or multifilament in form; it may be provided uncoated or coated; and it may be undyed or dyed with an appropriate FDA listed color additive. Also, the suture may be provided with or without a standard needle attached.
I.5030	Natural nonabsorbable silk surgical suture	2	Natural nonabsorbable silk surgical suture is a nonabsorbable, sterile, flexible multifilament thread composed of an organic protein called fibroin. This protein is derived from the domesticated speciesBombyx mori (B. mori) of the familyBombycidae. Natural nonabsorbable silk surgical suture is indicated for use in soft tissue approximation. Natural nonabsorbable silk surgical suture meets the United States Pharmacopeia (U.S.P.) monograph requirements for Nonabsorbable Surgical Suture (class I). Natural nonabsorbable silk surgical suture may be braided or twisted; it may be provided uncoated or coated; and it may be undyed or dyed with an FDA listed color additive.
I.5035	Nonabsorbable expanded polytetrafluoroethylene surgical suture	2	Nonabsorbable expanded polytetrafluoroethylene (ePTFE) surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from ePTFE and is intended for use in soft tissue approximation and ligation, including cardiovascular surgery. It may be undyed or dyed with an approved color additive and may be provided with or without an attached needle(s).

I.5040	Suction lipoplasty system	2	A suction lipoplasty system is a device intended for aesthetic body contouring. The device consists of a powered suction pump (containing a microbial filter on the exhaust and a microbial in-line filter in the connecting tubing between the collection bottle and the safety trap), collection bottle, cannula, and connecting tube. The microbial filters, tubing, collection bottle, and cannula must be capable of being changed between patients. The powered suction pump has a motor with a minimum of 1/3 horsepower, a variable vacuum range from 0 to 29.9 inches of mercury, vacuum control valves to regulate the vacuum with accompanying vacuum gauges, a single or double rotary vane (with or without oil), a single or double diaphragm, a single or double piston, and a safety trap.
I.5070	Air-handling apparatus for a surgical operating room	2	Air-handling apparatus for a surgical operating room is a device intended to produce a directed, nonturbulent flow of air that has been filtered to remove particulate matter and microorganisms to provide an area free of contaminants to reduce the possibility of infection in the patient.
I.5350	Needle-type epilator	1	A needle-type epilator is a device intended to destroy the dermal papilla of a hair by applying electric current at the tip of a fine needle that has been inserted close to the hair shaft, under the skin, and into the dermal papilla. The electric current may be high-frequency AC current, high-frequency AC combined with DC current, or DC current only.
I.5360	Tweezer-type epilator	1	The tweezer-type epilator is an electrical device intended to remove hair. The energy provided at the tip of the tweezer used to remove hair may be radio frequency, galvanic (direct current), or a combination of radio frequency and galvanic energy.
I.5400	Low level laser system	2	A Low Level Laser System is a device using low level laser energy for the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for noninvasive use. Classification. Class II
I.5650	Topical oxygen chamber for extremities	3	A topical oxygen chamber for extremities is a device intended to surround hermetically a patient's limb and apply humidified oxygen topically at a pressure slightly greater than atmospheric pressure to aid healing of chronic skin ulcers or bed sores.
I.5900	Nonpneumatic tourniquet	1	A nonpneumatic tourniquet is a device consisting of a strap or tubing intended to be wrapped around a patient's limb and tightened to reduce circulation.
I.5910	Pneumatic tourniquet	1	A pneumatic tourniquet is an air-powered device consisting of a pressure-regulating unit, connecting tubing, and an inflatable cuff. The cuff is intended to be wrapped around a patient's limb and inflated to reduce or totally occlude circulation during surgery.
I.9999	Others(General and Plastic Surgery Devices)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.

J.0001	Wound irrigation saline	2	Wound irrigation saline is a normal saline solution which uses physical means to clean the surface of a shallow skin wound.
J.0003	Elastic Pressure Garment	1	Elastic pressure garments apply to the skin surface and insert moderate and balanced pressure to support and compress the medical equipment covered on the patient's body parts, so as to achieve the effect of pressure medical treatment.
J.0004	Ozone Disinfector	2	Disinfect medical devices by generating ozone gas or ozone water.
J.2200	Liquid crystal forehead temperature strip	1	A liquid crystal forehead temperature strip is a device applied to the forehead that is used to indicate the presence or absence of fever, or to monitor body temperature changes. The device displays the color changes of heat sensitive liquid crystals corresponding to the variation in the surface temperature of the skin. The liquid crystals, which are cholesteric esters, are sealed in plastic.
J.2420	Electronic monitor for gravity flow infusion systems	2	An electronic monitor for gravity flow infusion systems is a device used to monitor the amount of fluid being infused into a patient. The device consists of an electronic transducer and equipment for signal amplification, conditioning, and display.
J.2460	Electrically powered spinal fluid pressure monitor	2	An electrically powered spinal fluid pressure monitor is an electrically powered device used to measure spinal fluid pressure by the use of a transducer which converts spinal fluid pressure into an electrical signal. The device includes signal amplification, conditioning, and display equipment.
J.2500	Spinal fluid manometer	2	A spinal fluid manometer is a device used to measure spinal fluid pressure. The device uses a hollow needle, which is inserted into the spinal column fluid space, to connect the spinal fluid to a graduated column so that the pressure can be measured by reading the height of the fluid.
J.2750	Image processing device for estimation of external blood loss	2	An image processing device for estimation of external blood loss is a device to be used as an aid in estimation of patient external blood loss. The device may include software and/or hardware that is used to process images capturing externally lost blood to estimate the hemoglobin mass and/or the blood volume present in the images.

J.2800	Sterilization process indicator	2	(a)Biological sterilization process indicator --(1)Identification: A biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of a known number of microorganisms, of known resistance to the mode of sterilization, in or on a carrier and enclosed in a protective package. Subsequent growth or failure of the microorganisms to grow under suitable conditions indicates the adequacy of sterilization. (2)Classification: Class 2. (b)Physical/chemical sterilization process indicator --(1)Identification: A physical/chemical sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor one or more parameters of the sterilization process. The adequacy of the sterilization conditions as measured by these parameters is indicated by a visible change in the device. (2)Classification: Class 2.
J.2900	Clinical color change thermometer	1	A clinical color change thermometer is a disposable device used to measure a patient's oral, rectal, or axillary (armpit) body temperature. The device records body temperature by use of heat sensitive chemicals which are sealed at the end of a plastic or metal strip. Body heat causes a stable color change in the heat sensitive chemicals.
J.2910	Clinical electronic thermometer	2	A clinical electronic thermometer is a device used to measure the body temperature of a patient by means of a transducer coupled with an electronic signal amplification, conditioning, and display unit. The transducer may be in a detachable probe with or without a disposable cover.
J.2920	Clinical mercury thermometer	1	A clinical mercury thermometer is a device used to measure oral, rectal, or axillary (armpit) body temperature using the thermal expansion of mercury.
J.5025	I.V. container	2	An I.V. container is a container made of plastic or glass used to hold a fluid mixture to be administered to a patient through an intravascular administration set.
J.5045	Medical recirculating air cleaner	2	A medical recirculating air cleaner is a device used to remove particles from the air for medical purposes. The device may function by electrostatic precipitation or filtration.
J.5075	Elastic bandage	1,2	An elastic bandage is a device consisting of either a long flat strip or a tube of elasticized material that is used to support and compress a part of a patient's body.
J.5090	Liquid bandage	1,2	A liquid bandage is a sterile device that is a liquid, semiliquid, or powder and liquid combination used to cover an opening in the skin or as a dressing for burns. The device is also used as a topical skin protectant. Classification: (1)Class 2 devices that are intended for patients with class 3 burning wound, free sewing(replacing surgical suture), contain added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.；(2)Class 1 other devices.

J.5100	AC-powered adjustable hospital bed	1	An AC-powered adjustable hospital bed is a device intended for medical purposes that consists of a bed with a built-in electric motor and remote controls that can be operated by the patient to adjust the height and surface contour of the bed. The device includes movable and latchable side rails.
J.5110	Hydraulic adjustable hospital bed	1	A hydraulic adjustable hospital bed is a device intended for medical purposes that consists of a bed with a hydraulic mechanism operated by an attendant to adjust the height and surface contour of the bed. The device includes movable and latchable side rails.
J.5120	Manual adjustable hospital bed	1	A manual adjustable hospital bed is a device intended for medical purposes that consists of a bed with a manual mechanism operated by an attendant to adjust the height and surface contour of the bed. The device includes movable and latchable side rails.
J.5130	Infant radiant warmer	2	The infant radiant warmer is a device consisting of an infrared heating element intended to be placed over an infant to maintain the infant's body temperature by means of radiant heat. The device may also contain a temperature monitoring sensor, a heat output control mechanism, and an alarm system (infant temperature, manual mode if present, and failure alarms) to alert operators of a temperature condition over or under the set temperature, manual mode time limits, and device component failure, respectively. The device may be placed over a pediatric hospital bed or it may be built into the bed as a complete unit.
J.5140	Pediatric medical crib	1	A pediatric medical crib is intended for medical purposes for use with a pediatric patient that consists of an open crib, fixed end rails, movable and latchable side rail components, and possibly an accompanying mattress. The contour of the crib surface may be adjustable.
J.5150	Nonpowered flotation therapy mattress	1	A nonpowered flotation therapy mattress is a mattress intended for medical purposes which contains air, fluid, or other materials that have the functionally equivalent effect of supporting a patient and avoiding excess pressure on local body areas. The device is intended to treat or prevent decubitus ulcers (bed sores).
J.5160	Therapeutic medical binder	1	A therapeutic medical binder is a device, usually made of cloth, that is intended for medical purposes and that can be secured by ties so that it supports the underlying part of the body or holds a dressing in place. This generic type of device includes the abdominal binder, breast binder, and perineal binder.
J.5180	Burn sheet	1,2	A burn sheet is a device made of a porous material that is wrapped aroung a burn victim to retain body heat, to absorb wound exudate, and to serve as a barrier against contaminants.
J.5200	Intravascular catheter	2	An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings and that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. The device may be constructed of metal, rubber, plastic, or a combination of these materials.

J.5210	Intravascular catheter securement device	1	An intravascular catheter securement device is a device with an adhesive backing that is placed over a needle or catheter and is used to keep the hub of the needle or the catheter flat and securely anchored to the skin.
J.5240	Medical adhesive tape and adhesive bandage	1,2	A medical adhesive tape or adhesive bandage is a device intended for medical purposes that consists of a strip of fabric material or plastic, coated on one side with an adhesive, and may include a pad of surgical dressing without a disinfectant. The device is used to cover and protect wounds, to hold together the skin edges of a wound, to support an injured part of the body, or to secure objects to the skin. Classification: (1)Class 2 devices that are intended for patients with class 3 burning wound, free sewing(replacing surgical suture), contain added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.；(2)Class 1 other devices.
J.5270	Neonatal eye pad	1	A neonatal eye pad is an opaque device used to cover and protect the eye of an infant during therapeutic procedures, such as phototherapy.
J.5300	Medical absorbent fiber	1	A medical absorbent fiber is a device intended for medical purposes that is made from cotton or synthetic fiber in the shape of a ball or a pad and that is used for applying medication to, or absorbing small amounts of body fluids from, a patient's body surface. Absorbent fibers intended solely for cosmetic purposes are not included in this generic device category.
J.5400	Neonatal incubator	2	A neonatal incubator is a device consisting of a rigid boxlike enclosure in which an infant may be kept in a controlled environment for medical care. The device may include an AC-powered heater, a fan to circulate the warmed air, a container for water to add humidity, a control valve through which oxygen may be added, and access ports for nursing care.
J.5410	Neonatal transport incubator	2	A neonatal transport incubator is a device consisting of a portable rigid boxlike enclosure with insulated walls in which an infant may be kept in a controlled environment while being transported for medical care. The device may include straps to secure the infant, a battery-operated heater, an AC-powered battery charger, a fan to circulate the warmed air, a container for water to add humidity, and provision for a portable oxygen bottle.
J.5420	Pressure infusor for an I.V. bag	1	A pressure infusor for an I.V. bag is a device consisting of an inflatable cuff which is placed around an I.V. bag. When the device is inflated, it increases the pressure on the I.V. bag to assist the infusion of the fluid.
J.5430	Nonelectrically powered fluid injector	2	A nonelectrically powered fluid injector is a nonelectrically powered device used by a health care provider to give a hypodermic injection by means of a narrow, high velocity jet of fluid which can penetrate the surface of the skin and deliver the fluid to the body. It may be used for mass inoculations.

J.5440	Intravascular administration set	2	An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.
J.5450	Patient care reverse isolation chamber	2	A patient care reverse isolation chamber is a device consisting of a roomlike enclosure designed to prevent the entry of harmful airborne material. This device protects a patient who is undergoing treatment for burns or is lacking a normal immunosuppressive defense due to therapy or congenital abnormality. The device includes fans and air filters which maintain an atmosphere of clean air at a pressure greater than the air pressure outside the enclosure.
J.5475	Jet lavage	1	A jet lavage is a device used to clean a wound by a pulsatile jet of sterile fluid. The device consists of the pulsing head, tubing to connect to a container of sterile fluid, and a means of propelling the fluid through the tubing, such as an electric roller pump.
J.5500	AC-powered patient lift	1	An AC-powered lift is an electrically powered device either fixed or mobile, used to lift and transport patients in the horizontal or other required position from one place to another, as from a bed to a bath. The device includes straps and slings to support the patient.
J.5510	Non-AC-powered patient lift	1	A non-AC-powered patient lift is a hydraulic, battery, or mechanically powered device, either fixed or mobile, used to lift and transport a patient in the horizontal or other required position from one place to another, as from a bed to a bath. The device includes straps and a sling to support the patient.
J.5550	Alternating pressure air flotation mattress	1	An alternating pressure air flotation mattress is a device intended for medical purposes that consists of a mattress with multiple air cells that can be filled and emptied in an alternating pattern by an associated control unit to provide regular, frequent, and automatic changes in the distribution of body pressure. The device is used to prevent and treat decubitus ulcers (bed sores).
J.5560	Temperature regulated water mattress	1	A temperature regulated water mattress is a device intended for medical purposes that consists of a mattress of suitable size, filled with water which can be heated or in some cases cooled. The device includes electrical heating and water circulating components, and an optional cooling component. The temperature control may be manual or automatic.
J.5570	Hypodermic single lumen needle	2	A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set.

J.5580	Acupuncture needle	2	An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.
J.5680	Pediatric position holder	1	A pediatric position holder is a device used to hold an infant or a child in a desired position for therapeutic or diagnostic purposes, e.g., in a crib under a radiant warmer, or to restrain a child while an intravascular injection is administered.
J.5700	Neonatal phototherapy unit	2	A neonatal phototherapy unit is a device used to treat or prevent hyperbilirubinemia (elevated serum bilirubin level). The device consists of one or more lamps that emit a specific spectral band of light, under which an infant is placed for therapy. This generic type of device may include supports for the patient and equipment and component parts.
J.5725	Infusion pump	2	An infusion pump is a device used in a health care facility to pump fluids into a patient in a controlled manner. The device may use a piston pump, a roller pump, or a peristaltic pump and may be powered electrically or mechanically. The device may also operate using a constant force to propel the fluid through a narrow tube which determines the flow rate. The device may include means to detect a fault condition, such as air in, or blockage of, the infusion line and to activate an alarm.
J.5740	Suction snakebite kit	1	A suction snakebite kit is a device consisting of a knife, suction device, and tourniquet used for first-aid treatment of snakebites by removing venom from the wound.
J.5760	Chemical cold pack snakebite kit	3	A chemical cold pack snakebit kit is a device consisting of a chemical cold pack and tourniquet used for first-aid treatment of snakebites.
J.5780	Medical support stocking	1,2	(a)Medical support stocking to prevent the pooling of blood in the legs --(1)Identification: A medical support stocking to prevent the pooling of blood in the legs is a device that is constructed of elastic material and designed to apply controlled pressure to the leg and that is intended for use in the prevention of pooling of blood in the leg. (2)Classification: Class 2. (b)Medical support stocking for general medical purposes --(1)Identification: A medical support stocking for general medical purposes is a device that is constructed of elastic material and designed to apply controlled pressure to the leg and that is intended for medical purposes other than the prevention of pooling of blood in the leg. (2) Classification: Class 1.
J.5820	Therapeutic scrotal support	1	A therapeutic scrotal support is a device intended for medical purposes that consist of a pouch attached to an elastic waistband and that is used to support the scrotum (the sac that contains the testicles).

J.5860	Piston syringe	2	A piston syringe is a device intended for medical purposes that consists of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male connector (nozzle) for fitting the female connector (hub) of a hypodermic single lumen needle. The device is used to inject fluids into, or withdraw fluids from, the body.
J.5950	Umbilical occlusion device	1	An umbilical occlusion device is a clip, tie, tape, or other article used to close the blood vessels in the umbilical cord of a newborn infant.
J.5965	Subcutaneous, implanted, intravascular infusion port and catheter	2	A subcutaneous, implanted, intravascular infusion port and catheter is a device that consists of a subcutaneous, implanted reservoir that connects to a long-term intravascular catheter. The device allows for repeated access to the vascular system for the infusion of fluids and medications and the sampling of blood. The device consists of a portal body with a resealable septum and outlet made of metal, plastic, or combination of these materials and a long-term intravascular catheter is either preattached to the port or attached to the port at the time of device placement. The device is available in various profiles and sizes and can be of a single or multiple lumen design.
J.5970	Percutaneous, implanted, long-term intravascular catheter	2	A percutaneous, implanted, long-term intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings, such as luer hubs, and accessories that facilitate the placement of the device. The device allows for repeated access to the vascular system for long-term use of 30 days or more, and it is intended for administration of fluids, medications, and nutrients; the sampling of blood; and monitoring blood pressure and temperature. The device may be constructed of metal, rubber, plastic, composite materials, or any combination of these materials and may be of single or multiple lumen design.
J.6025	Absorbent tipped applicator	1	An absorbent tipped applicator is a device intended for medical purposes that consists of an absorbent swab on a wooden, paper, or plastic stick. The device is used to apply medications to, or to take specimens from, a patient.
J.6100	Ethylene oxide gas aerator cabinet	2	An ethyene oxide gas aerator cabinet is a device that is intended for use by a health care provider and consists of a cabinet with a ventilation system designed to circulate and exchange the air in the cabinet to shorten the time required to remove residual ethylene oxide (ETO) from wrapped medical devices that have undergone ETO sterilization. The device may include a heater to warm the circulating air.
J.6150	Ultrasonic cleaner for medical instruments	1	An ultrasonic cleaner for medical instruments is a device intended for cleaning medical instruments by the emission of high frequency soundwaves.
J.6230	Tongue depressor	1	A tongue depressor is a device intended to displace the tongue to facilitate examination of the surrounding organs and tissues.

J.6250	Patient examination glove	1	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.Materials of patient examination gloves should comply with the barrier property (water leak) and tensile strength requirements of ISO 11193-1, ASTM D 3578, ASTM D 5250, ASTM D 6319, EN 455 or equivalent standards.A non-powdered (powder free) patient examination glove should comply with residual powders requirements of EN ISO 21171, ASTM D 6124 or equivalent standards. The amount of residual powders on a glove should not exceed 2.0 mg.
J.6280	Medical insole	1	A medical insole is a device intended for medical purposes that is placed inside a shoe to relieve the symptoms of athlete's foot infection by absorbing moisture.
J.6300	Implantable radiofrequency transponder system for patient identification and health information	2	An implantable radiofrequency transponder system for patient identification and health information is a device intended to enable access to secure patient identification and corresponding health information. This system may include a passive implanted transponder, inserter, and scanner. The implanted transponder is used only to store a unique electronic identification code that is read by the scanner. The identification code is used to access patient identity and corresponding health information stored in a database.
J.6375	Patient lubricant	1	A patient lubricant is a device intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device.
J.6430	Liquid medication dispenser	1	A Liquid medication dispenser is a device intended for medical purposes that is used to issue a measured amount of liquid medication.
J.6450	Skin pressure protectors	1	A skin pressure protector is a device intended for medical purposes that is used to reduce pressure on the skin over a bony prominence to reduce the likelihood of the patient's developing decubitus ulcers (bedsores).
J.6600	Ultraviolet (UV) radiation chamber disinfection device	2	An ultraviolet (UV) radiation chamber disinfection device is intended for the low-level surface disinfection of non-porous equipment surfaces by dose-controlled UV irradiation. This classification does not include self-contained open chamber UV radiation disinfection devices intended for whole room disinfection in a health care environment.
J.6740	Vacuum-powered body fluid suction apparatus	1	A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids. The device is powered by an external source of vacuum. This generic type of device includes vacuum regulators, vacuum collection bottles, suction catheters and tips, connecting flexible aspirating tubes, rigid suction tips, specimen traps, noninvasive tubing, and suction regulators (with gauge).
J.6775	Powered patient transfer device	1	A powered patient transfer device is a device consisting of a wheeled stretcher and a powered mechanism that has a broad, flexible band stretched over long rollers that can advance itself under a patient and transfer the patient with minimal disturbance in a horizontal position to the stretcher.

J.6785	Manual patient transfer device	1	A manual patient transfer device is a device consisting of a wheeled stretcher and a mechanism on which a patient can be placed so that the patient can be transferred with minimal disturbance in a horizontal position to the stretcher.
J.6820	Medical disposable scissors	1	Medical disposable scissors are disposable type general cutting devices intended for medical purposes. This generic type of device does not include surgical scissors.
J.6850	Sterilization wrap	2	A sterilization wrap (pack, sterilization wrapper, bag, or accessories, is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.
J.6860	Ethylene oxide gas sterilizer	2	An ethylene gas sterilizer is a nonportable device intended for use by a health care provider that uses ethylene oxide (ETO) to sterilize medical products.
J.6870	Dry-heat sterilizer	2	A dry-heat sterilizer is a device that is intended for use by a health care provider to sterilize medical products by means of dry heat.
J.6880	Steam sterilizer	2	A steam sterilizer (autoclave) is a device that is intended for use by a health care provider to sterilize medical products by means of pressurized steam.
J.6885	Liquid chemical sterilants/high level disinfectants	2	A liquid chemical sterilant/high level disinfectant is a germicide that is intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use. Critical devices make contact with normally sterile tissue or body spaces during use. Semicritical devices make contact during use with mucous membranes or nonintact skin.
J.6890	General purpose disinfectants	1	A general purpose disinfectant is a germicide intended to process noncritical medical devices and equipment surfaces. A general purpose disinfectant can be used to preclean or decontaminate critical or semicritical medical devices prior to terminal sterilization or high level disinfection. Noncritical medical devices make only topical contact with intact skin.
J.6900	Hand-carried stretcher	1	A hand-carried stretcher is a device consisting of a lightweight frame, or of two poles with a cloth or metal platform, on which a patient can be carried.
J.6910	Wheeled stretcher	1	A wheeled stretcher is a device consisting of a platform mounted on a wheeled frame that is designed to transport patients in a horizontal position. The device may have side rails, supports for fluid infusion equipment, and patient securement straps. The frame may be fixed or collapsible for use in an ambulance.
J.6920	Syringe needle introducer	2	A syringe needle introducer is a device that uses a spring-loaded mechanism to drive a hypodermic needle into a patient to a predetermined depth below the skin surface.

J.6960	Irrigating syringe	1	An irrigating syringe is a device intended for medical purposes that consists of a bulb or a piston syringe with an integral or a detachable tube. The device is used to irrigate, withdraw fluid from, or instill fluid into, a body cavity or wound.
J.6970	Liquid crystal vein locator	1	A liquid crystal vein locator is a device used to indicate the location of a vein by revealing variations in the surface temperature of the skin by displaying the color changes of heat sensitive liquid crystals (cholesteric esters).
J.6980	Vein stabilizer	1	A vein stabilizer is a device consisting of a flat piece of plastic with two noninvasive prongs. The device is placed on the skin so that the prongs are on either side of a vein and hold it stable while a hypodermic needle is inserted into the vein.
J.6991	Medical washer	2	A medical washer is a device that is intended for general medical purposes to clean surgical instruments, anesthesia equipment, hollowware, and other medical devices.
J.6992	Medical washer-disinfector	2	A medical washer-disinfector is a device that is intended for general medical purposes to clean, decontaminate, disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.
J.9999	Others(General Hospital and Personal Use Devices)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.
K.1020	Rigidity analyzer	2	A rigidity analyzer is a device for quantifying the extent of the rigidity of a patient's limb to determine the effectiveness of drugs or other treatments.
K.1030	Ataxiagraph	1	An ataxiagraph is a device used to determine the extent of ataxia (failure of muscular coordination) by measuring the amount of swaying of the body when the patient is standing erect and with eyes closed.
K.1200	Two-point discriminator	1	A two-point discriminator is a device with points used for testing a patient's touch discrimination.
K.1240	Echoencephalograph	2	An echoencephalograph is an ultrasonic scanning device (including A-scan, B-scan, and doppler systems) that uses noninvasive transducers for measuring intracranial interfaces and blood flow velocity to and in the head.
K.1275	Electroconductive media	2	Electroconductive media are the conductive creams or gels used with external electrodes to reduce the impedance (resistance to alternating current) of the contact between the electrode surface and the skin.
K.1310	Cortical electrode	2	A cortical electrode is an electrode which is temporarily placed on the surface of the brain for stimulating the brain or recording the brain's electrical activity.
K.1320	Cutaneous electrode	2	A cutaneous electrode is an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.
K.1330	Depth electrode	2	A depth electrode is an electrode used for temporary stimulation of, or recording electrical signals at, subsurface levels of the brain.

K.1340	Nasopharyngeal electrode	2	A nasopharyngeal electrode is an electrode which is temporarily placed in the nasopharyngeal region for the purpose of recording electrical activity.
K.1350	Needle electrode	2	A needle electrode is a device which is placed subcutaneously to stimulate or to record electrical signals.
K.1400	Electroencephalograph	2	An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.
K.1420	Electroencephalogram EEG signal spectrum analyzer	1	An electroencephalogram (EEG) signal spectrum analyzer is a device used to display the frequency content or power spectral density of the electroencephalogram (EEG) signal.
K.1460	Nystagmograph	2	A nystagmograph is a device used to measure, record, or visually display the involuntary movements (nystagmus) of the eyeball.
K.1480	Neurological endoscope	2	A neurological endoscope is an instrument with a light source used to view the inside of the ventricles of the brain.
K.1500	Esthesiometer	1	An esthesiometer is a mechanical device which usually consists of a single rod or fiber which is held in the fingers of the physician or other examiner and which is used to determine whether a patient has tactile sensitivity.
K.1525	Tuning fork	1	A tuning fork is a mechanical device which resonates at a given frequency and is used to diagnose hearing disorders and to test for vibratory sense.
K.1540	Galvanic skin response measurement device	2	A galvanic skin response measurement device is a device used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin.
K.1550	Nerve conduction velocity measurement device	2	A nerve conduction velocity measurement device is a device which measures nerve conduction time by applying a stimulus, usually to a patient's peripheral nerve. This device includes the stimulator and the electronic processing equipment for measuring and displaying the nerve conduction time.
K.1560	Skin potential measurement device	2	A skin potential measurement device is a general diagnostic device used to measure skin voltage by means of surface skin electrodes.
K.1570	Powered direct-contact temperature measurement device	2	A powered direct-contact temperature measurement device is a device which contains a power source and is used to measure differences in temperature between two points on the body.
K.1580	Non-electroencephalogram (non-EEG) physiological signal based seizure monitoring system	2	A non-electroencephalogram (non-EEG) physiological signal based seizure monitoring system is a noninvasive prescription device that collects physiological signals other than EEG to identify physiological signals that may be associated with a seizure.
K.1610	Alpha monitor	2	An alpha monitor is a device with electrodes that are placed on a patient's scalp to monitor that portion of the electroencephalogram which is referred to as the alpha wave.

K.1620	Intracranial pressure monitoring device	2	An intracranial pressure monitoring device is a device used for short-term monitoring and recording of intracranial pressures and pressure trends. The device includes the transducer, monitor, and interconnecting hardware.
K.1630	Cranial motion measurement device	2	A cranial motion measurement device is a prescription device that utilizes accelerometers to measure the motion or acceleration of the skull. These measurements are not to be used for diagnostic purposes.
K.1750	Pinwheel	1	A pinwheel is a device with sharp points on a rotating wheel used for testing pain sensation.
K.1790	Ocular plethysmograph	3	An ocular plethysmograph is a device used to measure or detect volume changes in the eye produced by pulsations of the artery, to diagnose carotid artery occlusive disease (restrictions on blood flow in the carotid artery).
K.1825	Rheoencephalograph	3	A rheoencephalograph is a device used to estimate a patient's cerebral circulation (blood flow in the brain) by electrical impedance methods with direct electrical connections to the scalp or neck area.
K.1835	Physiological signal amplifier	2	A physiological signal amplifier is a general purpose device used to electrically amplify signals derived from various physiological sources (e.g., the electroencephalogram).
K.1845	Physiological signal conditioner	2	A physiological signal conditioner is a device such as an integrator or differentiator used to modify physiological signals for recording and processing.
K.1855	Electroencephalogram (EEG) telemetry system	2	An electroencephalogram (EEG) telemetry system consists of transmitters, receivers, and other components used for remotely monitoring or measuring EEG signals by means of radio or telephone transmission systems.
K.1870	Evoked response electrical stimulator	2	An evoked response electrical stimulator is a device used to apply an electrical stimulus to a patient by means of skin electrodes for the purpose of measuring the evoked response.
K.1880	Evoked response mechanical stimulator	2	An evoked response mechanical stimulator is a device used to produce a mechanical stimulus or a series of mechanical stimuli for the purpose of measuring a patient's evoked response.
K.1890	Evoked response photic stimulator	2	An evoked response photic stimulator is a device used to generate and display a shifting pattern or to apply a brief light stimulus to a patient's eye for use in evoked response measurements or for electroencephalogram (EEG) activation.
K.1900	Evoked response auditory stimulator	2	An evoked response auditory stimulator is a device that produces a sound stimulus for use in evoked response measurements or electroencephalogram activation.
K.1935	Near infared (NIR) brain hematoma detector	2	A Near Infrared (NIR) Brain Hematoma Detector is a noninvasive device that employs near-infrared spectroscopy that is intended to be used to evaluate suspected brain hematomas. Classification. Class II
K.1950	Tremor transducer	2	A tremor transducer is a device used to measure the degree of tremor caused by certain diseases.
K.4030	Skull plate anvil	1	A skull plate anvil is a device used to form alterable skull plates in the proper shape to fit the curvature of a patient's skull.

K.4060	Ventricular cannula	1	A ventricular cannula is a device used to puncture the ventricles of the brain for aspiration or for injection. This device is frequently referred to as a ventricular needle.
K.4100	Ventricular catheter	2	A ventricular catheter is a device used to gain access to the cavities of the brain for injection of material into, or removal of material from, the brain.
K.4125	Neurosurgical chair	1	A neurosurgical chair is an operating room chair used to position and support a patient during neurosurgery.
K.4150	Scalp clip	2	A scalp clip is a plastic or metal clip used to stop bleeding during surgery on the scalp.
K.4175	Aneurysm clip applier	2	An aneurysm clip applier is a device used by the surgeon for holding and applying intracranial aneurysm clips.
K.4190	Clip forming/cutting instrument	1	A clip forming/cutting instrument is a device used by the physician to make tissue clips from wire stock.
K.4200	Clip removal instrument	1	A clip removal instrument is a device used to remove surgical clips from the patient.
K.4250	Cryogenic surgical device	2	A cryogenic surgical device is a device used to destroy nervous tissue or produce lesions in nervous tissue by the application of extreme cold to the selected site.
K.4275	Dowel cutting instrument	2	A dowel cutting instrument is a device used to cut dowels of bone for bone grafting.
K.4300	Manual cranial drills,burrs,trephines,and their accessories	2	Manual cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments that are used without a power source on a patient's skull.
K.4305	Powered compound cranial drills,burrs,trephines,and their accessories	2	Powered compound cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used on a patient's skull. The instruments employ a clutch mechanism to disengage the tip of the instrument after penetrating the skull to prevent plunging of the tip into the brain.
K.4310	Powered simple cranial drills,burrs,trephines,and their accessories	2	Powered simple cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used on a patient's skull. The instruments are used with a power source but do not have a clutch mechanism to disengage the tip after penetrating the skull.
K.4325	Cranial drill handpiece (brace)	1	A cranial drill handpiece (brace) is a hand holder, which is used without a power source, for drills, burrs, trephines, or other cutting tools that are used on a patient's skull.
K.4360	Electric cranial drill motor	2	An electric cranial drill motor is an electrically operated power source used with removable rotating surgical cutting tools or drill bits on a patient's skull.
K.4370	Pneumatic cranial drill motor	2	A pneumatic cranial drill motor is a pneumatically operated power source used with removable rotating surgical cutting tools or drill bits on a patient's skull.
K.4400	Radiofrequency lesion generator	2	A radiofrequency lesion generator is a device used to produce lesions in the nervous system or other tissue by the direct application of radiofrequency currents to selected sites.
K.4460	Neurosurgical head holder (skull clamp)	2	A neurosurgical head holder (skull clamp) is a device used to clamp the patient's skull to hold head and neck in a particular position during surgical procedures.

K.4500	Cranioplasty material forming instrument	1	A cranioplasty material forming instrument is a roller used in the preparation and forming of cranioplasty (skull repair) materials.
K.4525	Microsurgical instrument	1	A microsurgical instrument is a nonpowered surgical instrument used in neurological microsurgery procedures.
K.4535	Nonpowered neurosurgical instrument	1	A nonpowered neurosurgical instrument is a hand instrument or an accessory to a hand instrument used during neurosurgical procedures to cut, hold, or manipulate tissue. It includes specialized chisels, osteotomes, curettes, dissectors, elevators, forceps, gouges, hooks, surgical knives, rasps, scissors, separators, spatulas, spoons, blades, blade holders, blade breakers, probes, etc.
K.4545	Shunt system implantation instrument	1	A shunt system implantation instrument is an instrument used in the implantation of cerebrospinal fluid shunts, and includes tunneling instruments for passing shunt components under the skin.
K.4560	Stereotaxic instrument	2	A stereotaxic instrument is a device consisting of a rigid frame with a calibrated guide mechanism for precisely positioning probes or other devices within a patient's brain, spinal cord, or other part of the nervous system.
K.4600	Leukotome	1	A leukotome is a device used to cut sections out of the brain.
K.4650	Neurosurgical suture needle	1	A neurosurgical suture needle is a needle used in suturing during neurosurgical procedures or in the repair of nervous tissue.
K.4700	Cottonoid paddie	2	A neurosurgical paddie is a pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.
K.4725	Radiofrequency lesion probe	2	A radiofrequency lesion probe is a device connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired.
K.4750	Skull punch	1	A skull punch is a device used to punch holes through a patient's skull to allow fixation of cranioplasty plates or bone flaps by wire or other means.
K.4800	Self-retaining retractor for neurosurgery	2	A self-retaining retractor for neurosurgery is a self-locking device used to hold the edges of a wound open during neurosurgery.
K.4840	Manual rongeur	2	A manual rongeur is a manually operated instrument used for cutting or biting bone during surgery involving the skull or spinal column.
K.4845	Powered rongeur	2	A powered rongeur is a powered instrument used for cutting or biting bone during surgery involving the skull or spinal column.
K.4900	Skullplate screwdriver	1	A skullplate screwdriver is a tool used by the surgeon to fasten cranioplasty plates or skullplates to a patient's skull by screws.
K.5030	Methyl methacrylate for aneurysmorrhaphy	2	Methyl methacrylate for aneurysmorrhaphy (repair of aneurysms, which are balloonlike sacs formed on blood vessels) is a self-curing acrylic used to encase and reinforce intracranial aneurysms that are not amenable to conservative management, removal, or obliteration by aneurysm clip.

K.5050	Biofeedback device	2	A biofeedback device is an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters.
K.5070	Bite block	2	A bite block is a device inserted into a patient's mouth to protect the tongue and teeth while the patient is having convulsions.
K.5150	Intravascular occluding catheter	3	An intravascular occluding catheter is a catheter with an inflatable or detachable balloon tip that is used to block a blood vessel to treat malformations, e.g., aneurysms (balloonlike sacs formed on blood vessels) of intracranial blood vessels.
K.5175	Cartoid artery clamp	2	A carotid artery clamp is a device that is surgically placed around a patient's carotid artery (the principal artery in the neck that supplies blood to the brain) and has a removable adjusting mechanism that protrudes through the skin of the patient's neck. The clamp is used to occlude the patient's carotid artery to treat intracranial aneurysms (balloonlike sacs formed on blood vessels) or other intracranial vascular malformations that are difficult to attach directly by reducing the blood pressure and blood flow to the aneurysm or malformation.
K.5200	Aneurysm clip	2	An aneurysm clip is a device used to occlude an intracranial aneurysm (a balloonlike sac formed on a blood vessel) to prevent it from bleeding or bursting.
K.5225	Implanted malleable clip	2	An implanted malleable clip is a bent wire or staple that is forcibly closed with a special instrument to occlude an intracranial blood vessel or aneurysm (a balloonlike sac formed on a blood vessel), stop bleeding, or hold tissue or a mechanical device in place in a patient.
K.5235	Aversive conditioning device	2	An aversive conditioning device is an instrument used to administer an electrical shock or other noxious stimulus to a patient to modify undesirable behavioral characteristics.
K.5250	Burr hole cover	2	A burr hole cover is a plastic or metal device used to cover or plug holes drilled into the skull during surgery and to reattach cranial bone removed during surgery.
K.5275	Nerve cuff	2	A nerve cuff is a tubular silicone rubber sheath used to encase a nerve for aid in repairing the nerve (e.g., to prevent ingrowth of scar tissue) and for capping the end of the nerve to prevent the formation of neuroma (tumors).
K.5300	Methyl methacrylate for cranioplasty	2	Methyl methacrylate for cranioplasty (skull repair) is a self-curing acrylic that a surgeon uses to repair a skull defect in a patient. At the time of surgery, the surgeon initiates polymerization of the material and forms it into a plate or other appropriate shape to repair the defect.
K.5320	Preformed alterable cranioplasty plate	2	A preformed alterable cranioplasty plate is a device that is implanted into a patient to repair a skull defect. It is constructed of a material, e.g., tantalum, that can be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

K.5330	Preformed nonalterable cranioplasty plate	2	A preformed nonalterable cranioplasty plate is a device that is implanted in a patient to repair a skull defect and is constructed of a material, e.g., stainless steel or vitallium, that cannot be altered or reshaped at the time of surgery without changing the chemical behavior of the material.
K.5360	Cranioplasty plate fastener	2	A cranioplasty plate fastener is a screw, wire, or other article made of tantalum, vitallium, or stainless steel used to secure a plate to the patient's skull to repair a skull defect.
K.5500	Lesion temperature monitor	2	A lesion temperature monitor is a device used to monitor the tissue temperature at the site where a lesion (tissue destruction) is to be made when a surgeon uses a radiofrequency (RF) lesion generator and probe.
K.5550	Central nervous system fluid shunt and components	2	A central nervous system fluid shunt is a device or combination of devices used to divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial pressure or fluid volume (e.g., due to hydrocephalus). Components of a central nervous system shunt include catheters, valved catheters, valves, connectors, and other accessory components intended to facilitate use of the shunt or evaluation of a patient with a shunt.
K.5600	Neurovascular mechanical thrombectomy device for acute ischemic stroke treatment	2	A neurovascular mechanical thrombectomy device for acute ischemic stroke treatment is a prescription device used in the treatment of acute ischemic stroke to improve clinical outcomes. The device is delivered into the neurovasculature with an endovascular approach, mechanically removes thrombus from the body, and restores blood flow in the neurovasculature.
K.5800	Cranial electrotheraphy stimulator	3	A cranial electrotherapy stimulator is a device that applies electrical current to a patient's head to treat insomnia, depression, or anxiety.
K.5801	Computerized behavioral therapy device for psychiatric disorders	2	A computerized behavioral therapy device for psychiatric disorders is a prescription only device intended to provide a computerized version of condition-specific behavioral therapy as an adjunct to clinician supervised outpatient treatment to patients with psychiatric conditions. The digital therapy is intended to provide patients access to therapy tools used during treatment sessions to improve recognized treatment outcomes.
K.5805	Repetitive transcranial magnetic stimulation system	2	A repetitive transcranial magnetic stimulation system is an external device that delivers transcranial repetitive pulsed magnetic fields of sufficient magnitude to induce neural action potentials in the prefrontal cortex to treat the symptoms of major depressive disorder. Classification. Class II
K.5810	External functional neuromuscular stimulator	2	An external functional neuromuscular stimulator is an electrical stimulator that uses external electrodes for stimulating muscles in the leg and ankle of partially paralyzed patients (e.g., after stroke) to provide flexion of the foot and thus improve the patient's gait.

K.5820	Implanted cerebellar stimulator	3	An implanted cerebellar stimulator is a device used to stimulate electrically a patient's cerebellar cortex for the treatment of intractable epilepsy, spasticity, and some movement disorders. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's cerebellum and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.
K.5830	Implanted diaphragmatic/phrenic nerve stimulator	3	An implanted diaphragmatic/phrenic nerve stimulator is a device that provides electrical stimulation of a patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation (a state in which an abnormally low amount of air enters the lungs) caused by brain stem disease, high cervical spinal cord injury, or chronic lung disease. The stimulator consists of an implanted receiver with electrodes that are placed around the patient's phrenic nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.
K.5840	Implanted intracerebral/subcortical stimulator for pain relief	3	An implanted intracerebral/subcortical stimulator for pain relief is a device that applies electrical current to subsurface areas of a patient's brain to treat severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed within a patient's brain and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.
K.5850	Implanted spinal cord stimulator for bladder evacuation	3	An implanted spinal cord stimulator for bladder evacuation is an electrical stimulator used to empty the bladder of a paraplegic patient who has a complete transection of the spinal cord and who is unable to empty his or her bladder by reflex means or by the intermittent use of catheters. The stimulator consists of an implanted receiver with electrodes that are placed on the conus medullaris portion of the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.
K.5860	Implanted neuromuscular stimulator	3	An implanted neuromuscular stimulator is a device that provides electrical stimulation to a patient's peroneal or femoral nerve to cause muscles in the leg to contract, thus improving the gait in a patient with a paralyzed leg. The stimulator consists of an implanted receiver with electrodes that are placed around a patient's nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver. The external transmitter is activated by a switch in the heel in the patient's shoe.
K.5870	Implanted peripheral nerve stimulator for pain relief	2	An implanted peripheral nerve stimulator for pain relief is a device that is used to stimulate electrically a peripheral nerve in a patient to relieve severe intractable pain. The stimulator consists of an inplanted receiver with electrodes that are placed around a peripheral nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

K.5880	Implanted spinal cord stimulator for bladder evacuation	2,3	(a) An implanted spinal cord stimulator for bladder evacuation is an electrical stimulator used to empty the bladder of a paraplegic patient who has a complete transection of the spinal cord and who is unable to empty his or her bladder by reflex means or by the intermittent use of catheters. The stimulator consists of an implanted receiver with electrodes that are placed on the conus medullaris portion of the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver. (b) Classification: (1) Class 2 for devices intended to treat body/limbs cronical or intractable pain, (2) Class 3 for other devices (e.g., intended to treat pain caused from failed back surgery syndrome).
K.5890	Transcutaneous electrical nerve stimulator for pain relief	2	A transcutaneous electrical nerve stimulator for pain relief is a device used to apply an electrical current to electrodes on a patient's skin to treat pain.
K.5892	External vagal nerve stimulator for headache	2	An external vagal nerve stimulator for headache is a prescription device used to apply an electrical current to a patient's vagus nerve through electrodes placed on the skin for the treatment of headache.
K.5893	Thermal vestibular stimulator for headache	2	The thermal vestibular stimulator for headache is a prescription device used to stimulate the vestibular system by applying thermal waveforms through earpieces placed in a patient's ear canal for the treatment of headache.
K.5895	Vibratory counter-stimulation device	2	A vibratory counter-stimulation device is a prescription device that provides electrically powered mechanical vibration to improve the quality of sleep in patients with primary Restless Legs Syndrome.
K.5896	Percutaneous nerve stimulator for substance use disorders	2	A percutaneous nerve stimulator for substance use disorders is a device that stimulates nerves percutaneously to aid in the reduction of withdrawal symptoms associated with substance use disorders.
K.5897	External upper limb tremor stimulator	2	An external upper limb tremor stimulator is a prescription device which is placed externally on the upper limb and designed to aid in tremor symptom relief of the upper limb.
K.5900	Preformed craniosynostosis strip	2	A preformed craniosynostosis strip is a plastic strip used to cover bone edges of craniectomy sites (sites where the skull has been cut) to prevent the bone from regrowing in patients whose skull sutures are abnormally fused together.
K.5910	Dura substitute	2	A dura substitute is a sheet or material that is used to repair the dura mater (the membrane surrounding the brain).
K.5940	Electroconvulsive therapy device	3	An electroconvulsive therapy device is a device used for treating severe psychiatric disturbances (e.g., severe depression) by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head.
K.5950	Artificial embolization device	3	A neurovascular embolization device is an intravascular implant intended to permanently occlude blood flow to cerebral aneurysms and cerebral ateriovenous malformations. This does not include cyanoacrylates and other embolic agents, which act by polymerization or precipitation. Embolization devices used in other vascular applications are also not included in this classification, see 870.3300.

K.5960	Skull tongs for traction	2	Skull tongs for traction is an instrument used to immobilize a patient with a cervical spine injury (e.g., fracture or dislocation). The device is caliper shaped with tips that penetrate the skin. It is anchored to the skull and has a heavy weight attached to it that maintains, by traction, the patient's position.
K.5970	Cranial orthesis	2	A cranial orthosis is a device that is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.
K.9999	Others(Neurological Devices)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.
L.0001	Chorionic villus sampling set	3	The chorionic villus sampling set is a devide used to obtain a sample of chorionic tissue through the cervix.
L.0002	Uterine manipulator/injector cannula	2	The uterine manipulator/injector cannula is a device to deliver contrast media into the uterus and fallopian tubes for the evaluation of the fallopian tubes and/or the uterus.
L.0004	Absorable adhesion barrier	3	An absorbable adhesion barrier is used for patients undergoing open gynecologic surgery. This device is intended to reduce the likelihood of developing postoperative adnexal adhesions in these patients.
L.1040	Viscometer for cervical mucus	1	A viscometer for cervical mucus is a device that is intended to measure the relative viscoelasticity of cervical mucus collected from a female patient. Measurements of relative viscoelasticity are intended for use as an adjunct in the clinical evaluation of a female with chronic infertility, to determine the time of ovulation and the penetrability of cervical mucus to motile sperm.
L.1050	Endocervical aspirator	2	An endocervical aspirator is a device designed to remove tissue from the endocervix (mucous membrane lining the canal of the cervix of the uterus) by suction with a syringe, bulb and pipette, or catheter. This device is used to evaluate endocervical tissue to detect malignant and premalignant lesions.
L.1060	Endometrial aspirator	2	An endometrial aspirator is a device designed to remove materials from the endometrium (the mucosal lining of the uterus) by suction with a syringe, bulb and pipette, or catheter. This device is used to study endometrial cytology (cells).
L.1100	Endometrial brush	2	An endometrial brush is a device designed to remove samples of the endometrium (the mucosal lining of the uterus) by brushing its surface. This device is used to study endometrial cytology (cells).
L.1175	Endometrial suction curette and accessories	2	An endometrial suction curette is a device used to remove material from the uterus and from the mucosal lining of the uterus by scraping and vacuum suction. This device is used to obtain tissue for biopsy or for menstrual extraction. This generic type of device may include catheters, syringes, and tissue filters or traps.

L.1185	Endometrial washer	2	An endometrial washer is a device used to remove materials from the endometrium (the mucosal lining of the uterus) by washing with water or saline solution and then aspirating with negative pressure. This device is used to study endometrial cytology (cells).
L.1300	Uterotubal carbon dioxide insufflator and accessories	2	A uterotubal carbon dioxide insufflator and accessories is a device used to test the patency (lack of obstruction) of the fallopian tubes by pressurizing the uterus and fallopian tubes and filling them with carbon dioxide gas.
L.1425	Perineometer	2	A perineometer is a device consisting of a fluid-filled sack for intravaginal use that is attached to an external manometer. The devices measure the strength of the perineal muscles by offering resistence to a patient's voluntary contractions of these muscles and is used to diagnose and to correct, through exercise, uninary incontinence or sexual dysfunction.
L.1550	Amniotic fluid sampler amniocentesis tray	1	The amniotic fluid sampler (amniocentesis tray) is a collection of devices used to aspirate amniotic fluid from the amniotic sac via a transabdominal approach. Components of the amniocentesis tray include a disposable 3 inch 20 gauge needle with stylet and a 30 cc. syringe, as well as the various sample collection accessories, such as vials, specimen containers, medium, drapes, etc. The device is used at 16-18 weeks gestation for antepartum diagnosis of certain congenital abnormalities or anytime after 24 weeks gestation when used to assess fetal maturity.
L.1560	Fetal blood sampler	2	A fetal blood sampler is a device used to obtain fetal blood transcervically through an endoscope by puncturing the fetal skin with a short blade and drawing blood into a heparinized tube. The fetal blood pH is determined and used in the diagnosis of fetal distress and fetal hypoxia.
L.1600	Transabdominal amnioscope (fetoscope) and accessories	3	A transabdominal amnioscope is a device designed to permit direct visual examination of the fetus by a telescopic system via abdominal entry. The device is used to ascertain fetal abnormalities, to obtain fetal blood samples, or to obtain fetal tissue. This generic type of device may include the following accessories: trocar and cannula, instruments used through an operating channel or through a separate cannula associated with the amnioscope, light source and cables, and component parts.
L.1630	Colposcope	2	A colposcope is a device designed to permit direct viewing of the tissues of the vagina and cervix by a telescopic system located outside the vagina. It is used to diagnose abnormalities and select areas for biopsy. This generic type of device may include a light source, cables, and component parts.

L.1640	Culdoscope and accessories	1,2	Identification:A culdoscope is a device designed to permit direct viewing of the organs within the peritoneum by a telescopic system introduced into the pelvic cavity through the posterior vaginal fornix. It is used to perform diagnostic and surgical procedures on the female genital organs. This generic type of device may include trocar and cannula, instruments used through an operating channel, scope preheaters, light source and cables, and component parts. Classification:(1)Class 2；(2)Class 1 devices for culdoscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such culdoscope accessory instruments include: lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable) scissors, and suction/irrigation probe.
L.1660	Transcervical endoscope amnioscope and accessories	2	A transcervical endoscope is a device designed to permit direct viewing of the fetus and amniotic sac by means of an open tube introduced into the uterus through the cervix. The device may be used to visualize the fetus or amniotic fluid and to sample fetal blood or amniotic fluid. This generic type of device may include obturators, instruments used through an operating channel, light sources and cables, and component parts.
L.1690	Hysteroscope and accessories	1,2	Identification: A hysteroscope is a device used to permit direct viewing of the cervical canal and the uterine cavity by a telescopic system introduced into the uterus through the cervix. It is used to perform diagnostic and surgical procedures other than sterilization. This generic type of device may include obturators and sheaths, instruments used through an operating channel, scope preheaters, light sources and cables, and component parts. Classification: (1)Class 2；(2)Class 1 devices for hysteroscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such hysteroscope accessory instruments include: lens cleaning brush, cannula (without trocar or valves), clamp/hemostat/grasper, curette, instrument guide, forceps, dissector, mechanical (noninflatable), and scissors.
L.1700	Hysteroscopic insufflator	1,2	Identification: A hysteroscopic insufflator is a device designed to distend the uterus by filling the uterine cavity with a liquid or gas to facilitate viewing with a hysteroscope. Classification: (1) Class 2；(2) Class 1 devices for tubing and tubing/filter fits which only include accessory instruments that are not used to effect intrauterine access, e.g., hysteroscopic introducer sheaths, etc.; and single-use tubing kits used for only intrauterine insufflation.

L.1710	Closed loop hysteroscopic insufflator with cutter-coagulator	2	A closed loop hysteroscopic insufflator with cutter-coagulator is a prescription device configured for hysteroscopic insufflation, resection, and coagulation. It is used to perform diagnostic and surgical procedures (i.e., resection and coagulation). This device type contains a closed-loop recirculating fluid management system for the controlled delivery of filtered distension fluid. This device type also contains a bipolar radiofrequency device used in conjunction with a hysteroscope for resection and coagulation of intrauterine tissues.
L.1720	Gynecologic laparoscope and accessories	1,2	Identification:A gynecologic laparoscope is a device used to permit direct viewing of the organs within the peritoneum by a telescopic system introduced through the abdominal wall. It is used to perform diagnostic and surgical procedures on the female genital organs. This generic type of device may include: Trocar and cannula, instruments used through an operating channel, scope preheater, light source and cables, and component parts. Classification: (1) Class 2；(2) Class 1 devices for gynecologic laparoscope accessories that are not part of a specialized instrument or device delivery system, do not have adapters, connector channels, or do not have portals for electrosurgical, lasers, or other power sources. Such gynecologic laparosope accessory instruments include: the lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable), scissors, and suction/irrigation probe.
L.1730	Laparoscopic insufflator	1,2	(a) Identification: A laparoscopic insufflator is a device used to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it. (b) Classification: (1) Class 2; (2) Class 1: Tubing and tubing/filter kits which include accessory instruments that are not used to effect intra-abdominal insufflation (pneumoperitoneum).
L.2050	Obstetric data analyzer	3	An obstetric data analyzer (fetal status data analyzer) is a device used during labor to analyze electronic signal data obtained from fetal and maternal monitors. The obstetric data analyzer provides clinical diagnosis of fetal status and recommendations for labor management and clinical interventions. This generic type of device may include signal analysis and display equipment, electronic interfaces for other equipment, and power supplies and component parts.
L.2225	Obstetric-gynecologic ultrasonic imager	2	An obstetric-gynecologic ultrasonic imager is a device designed to transmit and receive ultrasonic energy into and from a female patient by pulsed echoscopy. This device is used to provide a visual representation of some physiological or artificial structure, or of a fetus, for diagnostic purposes during a limited period of time. This generic type of device may include the following: signal analysis and display equipment, electronic interfaces for other equipment, patient and equipment supports, coupling gel, and component parts. This generic type of device does not include devices used to monitor the changes in some physiological condition over long periods of time.

L.2600	Fetal cardiac monitor	2	A fetal cardiac monitor is a device used to ascertain fetal heart activity during pregnancy and labor. The device is designed to separate fetal heart signals from maternal heart signals by analyzing electrocardiographic signals (electrical potentials generated during contraction and relaxation of heart muscle) obtained from the maternal abdomen with external electrodes. This generic type of device may include an alarm that signals when the heart rate crosses a preset threshold. This generic type of device includes the "fetal cardiotachometer (with sensors)" and the "fetal electrocardiographic monitor."
L.2620	Fetal electroencephalographic monitor	3	A fetal electroencephalographic monitor is a device used to detect, measure, and record in graphic form (by means of one or more electrodes placed transcervically on the fetal scalp during labor) the rhythmically varying electrical skin potentials produced by the fetal brain.
L.2640	Fetal phonocardiographic monitor and accessories	2	A fetal phonocardiographic monitor is a device designed to detect, measure, and record fetal heart sounds electronically, in graphic form, and noninvasively, to ascertain fetal condition during labor. This generic type of device includes the following accessories: signal analysis and display equipment, patient and equipment supports, and other component parts.
L.2660	Fetal ultrasonic monitor and accessories	2	A fetal ultrasonic monitor is a device designed to transmit and receive ultrasonic energy into and from the pregnant woman, usually by means of continuous wave (doppler) echoscopy. The device is used to represent some physiological condition or characteristic in a measured value over a period of time (e.g., perinatal monitoring during labor) or in an immediately perceptible form (e.g., use of the ultrasonic stethoscope). This generic type of device may include the following accessories: signal analysis and display equipment, electronic interfaces for other equipment, patient and equipment supports, and component parts. This generic type of device does not include devices used to image some relatively unchanging physiological structure or interpret a physiological condition, but does include devices which may be set to alarm automatically at a predetermined threshold value.
L.2675	Fetal scalp circular spiral electrode and applicator	2	A fetal scalp circular (spiral) electrode and applicator is a device used to obtain a fetal electrocardiogram during labor and delivery. It establishes electrical contact between fetal skin and an external monitoring device by a shallow subcutaneous puncture of fetal scalp tissue with a curved needle or needles. This generic type of device includes nonreusable spiral electrodes and reusable circular electrodes.
L.2685	Fetal scalp clip electrode and applicator	3	A fetal scalp clip electrode and applicator is a device designed to establish electrical contact between fetal skin and an external monitoring device by means of pinching skin tissue with a nonreusable clip. This device is used to obtain a fetal electrocardiogram. This generic type of device may include a clip electrode applicator.

L.2700	Intrauterine pressure monitor and accessories	2	An intrauterine pressure monitor is a device designed to detect and measure intrauterine and amniotic fluid pressure with a catheter placed transcervically into the uterine cavity. The device is used to monitor intensity, duration, and frequency of uterine contractions during labor. This generic type of device may include the following accessories: signal analysis and display equipment, patient and equipment supports, and component parts.
L.2720	External uterine contraction monitor and accessories	2	An external uterine contraction monitor (i.e., the tokodynamometer) is a device used to monitor the progress of labor. It measures the duration, frequency, and relative pressure of uterine contractions with a transducer strapped to the maternal abdomen. This generic type of device may include an external pressure transducer, support straps, and other patient and equipment supports.
L.2730	Home uterine activity monitor	2	A home uterine activity monitor (HUAM) is an electronic system for at home antepartum measurement of uterine contractions, data transmission by telephone to a clinical setting, and for receipt and display of the uterine contraction data at the clinic. The HUAM system comprises a tocotransducer, an at-home recorder, a modem, and a computer and monitor that receive, process, and display data. This device is intended for use in women with a previous preterm delivery to aid in the detection of preterm labor.
L.2740	Perinatal monitoring system and accessories	2	A perinatal monitoring system is a device used to show graphically the relationship between maternal labor and the fetal heart rate by means of combining and coordinating uterine contraction and fetal heart monitors with appropriate displays of the well-being of the fetus during pregnancy, labor, and delivery. This generic type of device may include any of the devices subject to 884.2600, 884.2640, 884.2660, 884.2675, 884.2700, and 884.2720. This generic type of device may include the following accessories: Central monitoring system and remote repeaters, signal analysis and display equipment, patient and equipment supports, and component parts.
L.2800	Computerized Labor Monitoring System	2	A computerized labor monitoring system is a system intended to continuously measure cervical dilation and fetal head descent and provide a display that indicates the progress of labor. The computerized labor monitoring system includes a monitor and ultrasound transducers. Ultrasound transducers are placed on the maternal abdomen and cervix and on the fetal scalp to provide the matrix of measurements used to produce the display.
L.2900	Fetal stethoscope	1	A fetal stethoscope is a device used for listening to fetal heart sounds. It is designed to transmit the fetal heart sounds not only through sound channels by air conduction, but also through the user's head by tissue conduction into the user's ears. It does not use ultrasonic energy. This device is designed to eliminate noise interference commonly caused by handling conventional stethoscopes.

L.2960	Obstetric ultrasonic transducer and accessories	2	An obstetric ultrasonic transducer is a device used to apply ultrasonic energy to, and to receive ultrasonic energy from, the body in conjunction with an obstetric monitor or imager. The device converts electrical signals into ultrasonic energy, and vice versa, by means of an assembly distinct from an ultrasonic generator. This generic type of device may include the following accessories: coupling gel, preamplifiers, amplifiers, signal conditioners with their power supply, connecting cables, and component parts. This generic type of device does not include devices used to generate the ultrasonic frequency electrical signals for application.
L.2980	Telethermographic system	1,3	Identification: A telethermographic system for diagnostic screening for detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories. Classification: (1) Class 1 devices intended for adjunctive diagnostic screening for detection of breast cancer or other uses. (2)Class 3 devices for use alone in diagnostic screening for detection of breast cancer or other use.
L.2982	Liquid crystal thermographic system	1,3	(a)A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for adjunctive use in diagnostic screening for detection of breast cancer or other uses --(1)Identification. A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for use as an adjunct to physical palpation or mammography in diagnostic screening for detection of breast cancer or other uses is a nonelectrically powered or an AC-powered device applied to the skin that displays the color patterns of heat sensitive cholesteric liquid crystals that respond to temperature variations of the surface of the body. This generic type of device may include patient and equipment supports, a means to ensure thermal contact between the patient's skin and the liquid crystals, component parts, and accessories. (2)Classification. Class I (general controls).
L.3200	Cervical drain	2	A cervical drain is a device designed to provide an exit channel for draining discharge from the cervix after pelvic surgery.
L.3575	Vaginal pessary	2	A vaginal pessary is a removable structure placed in the vagina to support the pelvic organs and is used to treat conditions such as uterine prolapse (falling down of uterus), uterine retroposition (backward displacement), or gynecologic hernia.
L.3650	Fallopian tube prosthesis	2	A fallopian tube prosthesis is a device designed to maintain the patency (openness) of the fallopian tube and is used after reconstructive surgery.
L.3900	Vaginal stent	2	A vaginal stent is a device used to enlarge the vagina by stretching, or to support the vagina and to hold a skin graft after reconstructive surgery.

L.4050	Gynecologic laparoscopic power morcellation containment system	2	A gynecologic laparoscopic power morcellation containment system is a prescription device consisting of an instrument port and tissue containment method that creates a working space allowing for direct visualization during a power morcellation procedure following a laparoscopic procedure for the excision of benign gynecologic tissue that is not suspected to contain malignancy.
L.4100	Endoscopic electrocautery and accessories	2	An endoscopic electrocautery is a device used to perform female sterilization under endoscopic observation. It is designed to coagulate fallopian tube tissue with a probe heated by low-voltage energy. This generic type of device may include the following accessories: electrical generators, probes, and electrical cables.
L.4120	Gynecologic electrocautery and accessories	2	A gynecologic electrocautery is a device designed to destroy tissue with high temperatures by tissue contact with an electrically heated probe. It is used to excise cervical lesions, perform biopsies, or treat chronic cervicitis under direct visual observation. This generic type of device may include the following accessories: an electrical generator, a probe, and electrical cables.
L.4150	Bipolar endoscopic coagulator-cutter and accessories	2	A bipolar endoscopic coagulator-cutter is a device used to perform female sterilization and other operative procedures under endoscopic observation. It destroys tissue with high temperatures by directing a high frequency electrical current through tissue between two electrical contacts of a probe. This generic type of device may include the following accessories: an electrical generator, probes, and electrical cables.
L.4160	Unipolar endoscopic coagulator-cutter and accessories	2	A unipolar endoscopic coagulator-cutter is a device designed to destroy tissue with high temperatures by directing a high frequency electrical current through the tissue between an energized probe and a grounding plate. It is used in female sterilization and in other operative procedures under endoscopic observation. This generic type of device may include the following accessories: an electrical generator, probes and electrical cables, and a patient grounding plate. This generic type of device does not include devices used to perform female sterilization under hysteroscopic observation.
L.4250	Expandable cervical dilator	3	An expandable cervical dilator is an instrument with two handles and two opposing blades used manually to dilate (stretch open) the cervical os.
L.4260	Hygroscopic Laminaria cervical dilator	2	A hygroscopicLaminaria cervical dilator is a device designed to dilate (stretch open) the cervical os by cervical insertion of a conical and expansible material made from the root of a seaweed (Laminaria digitata orLaminaria japonica). The device is used to induce abortion.
L.4270	Vibratory cervical dilators	3	A vibratory cervical dilator is a device designed to dilate the cervical os by stretching it with a power-driven vibrating probe head. The device is used to gain access to the uterus or to induce abortion, but is not to be used during labor when a viable fetus is desired or anticipated.

L.4340	Fetal vacuum extractor	2	A fetal vacuum extractor is a device used to facilitate delivery. The device enables traction to be applied to the fetal head (in the birth canal) by means of a suction cup attached to the scalp and is powered by an external vacuum source. This generic type of device may include the cup, hosing, vacuum source, and vacuum control.
L.4350	Fetal head elevator	2	A fetal head elevator is a prescription device consisting of a mechanism that elevates the fetal head to facilitate delivery during a Caesarean section.
L.4400	Obstetric forceps	2	An obstetric forceps is a device consisting of two blades, with handles, designed to grasp and apply traction to the fetal head in the birth passage and facilitate delivery.
L.4500	Obstetric fetal destructive instrument	2	An obstetric fetal destructive instrument is a device designed to crush or pull the fetal body to facilitate the delivery of a dead or anomalous (abnormal) fetus. This generic type of device includes the cleidoclast, cranioclast, craniotribe, and destructive hook.
L.4520	Obstetric-gynecologic general manual instrument	1	An obstetric-gynecologic general manual instrument is one of a group of devices used to perform simple obstetric and gynecologic manipulative functions. This generic type of device consists of the following: (1) An episiotomy scissors is a cutting instrument, with two opposed shearing blades, used for surgical incision of the vulvar orifice for obstetrical purposes. (2) A fiberoptic metal vaginal speculum is a metal instrument, with fiberoptic light, used to expose and illuminate the interior of the vagina. (3) A metal vaginal speculum is a metal instrument used to expose the interior of the vagina. (4) An umbilical scissors is a cutting instrument, with two opposed shearing blades, used to cut the umbilical cord. (5) A uterine clamp is an instrument used to hold the uterus by compression. (6) A uterine packer is an instrument used to introduce dressing into the uterus or vagina. (7) A vaginal applicator is an instrument used to insert medication into the vagina. (8) A vaginal retractor is an instrument used to maintain vaginal exposure by separating the edges of the vagina and holding back the tissue. (9) A gynecological fibroid hook is an instrument used to exert traction upon a fibroid. (10) A pelvimeter (external) is an instrument used to measure the external diameters of the pelvis.

L.4530	Obstetric-gynecologic specialized manual instrument	1,2	An obstetric-gynecologic specialized manual instrument is one of a group of devices used during obstetric-gynecologic procedures to perform manipulative diagnostic and surgical functions (e.g., dilating, grasping, measuring, and scraping), where structural integrity is the chief criterion of device performance. This type of device consists of the following: (1) An amniotome is an instrument used to rupture the fetal membranes. (2) A circumcision clamp is an instrument used to compress the foreskin of the penis during circumcision of a male infant. (3) An umbilical clamp is an instrument used to compress the umbilical cord. (4) A uterine curette is an instrument used to scrape and remove material from the uterus. (5) A fixed-size cervical dilator is any of a series of bougies of various sizes used to dilate the cervical os by stretching the cervix. (6) A uterine elevator is an instrument inserted into the uterus used to lift and manipulate the uterus.\ (7) A gynecological surgical forceps is an instrument with two blades and handles used to pull, grasp, or compress during gynecological examination. (8) A cervical cone knife is a cutting instrument used to excise and remove tissue from the cervix. (9) A gynecological cerclage needle is a looplike instrument used to suture the cervix.(10) A hook-type contraceptive intrauterine device (IUD) remover is an instrument used to remove an IUD from the uterus. (11) A gynecological fibroid screw is an instrument used to hold onto a fibroid. (12) A uterine sound is an instrument used to determine the depth of the uterus by inserting it into the uterine cavity. (13) A cytological cervical spatula is a blunt instrument used to scrape and remove cytological material from the surface of the cervix or vagina. (14) A gynecological biopsy forceps is an instrument with two blades and handles used for gynecological biopsy procedures. (15) A uterine tenaculum is a hooklike instrument used to seize and hold the cervix or fundus. (16) An internal pelvimeter is an instrument used within the vagina to measure the diameter and capacity of the pelvis. (17) A nonmetal vaginal speculum is a nonmetal instrument used to expose the interior of the vagina. (18) A fiberoptic nonmetal vaginal speculum is a nonmetal instrument, with fiberoptic light, used to expose and illuminate the interior of the vagina. Classification: (1) Class 2；(2) Class 1 devices for the amniotome, uterine curette, cervical dilator (fixed-size bougies), cerclage needle, IUD remover, uterine sound, and gynecological biopsy forceps.

L.4550	Gynecologic surgical laser	2	A gynecologic surgical laser is a continuous wave carbon dioxide laser designed to destroy tissue thermally or to remove tissue by radiant light energy. The device is used only in conjunction with a colposcope as part of a gynecological surgical system. A colposcope is a magnifying lens system used to examine the vagina and cervix.
L.4900	Obstetric table and accessories	2	An obstetric table is a device with adjustable sections designed to support a patient in the various positions required during obstetric and gynecologic procedures. This generic type of device may include the following accessories: patient equipment, support attachments, and cabinets for warming instruments and disposing of wastes.
L.5050	Metreurynter-balloon abortion system	3	A metreurynter-balloon abortion system is a device used to induce abortion. The device is inserted into the uterine cavity, inflated, and slowly extracted. The extraction of the balloon from the uterus causes dilation of the cervical os. This generic type of device may include pressure sources and pressure controls.
L.5070	Vacuum abortion system	2	A vacuum abortion system is a device designed to aspirate transcervically the products of conception or menstruation from the uterus by using a cannula connected to a suction source. This device is used for pregnancy termination or menstrual regulation. This type of device may include aspiration cannula, vacuum source, and vacuum controller.
L.5100	Obstetric anesthesia set	2	An obstetric anesthesia set is an assembly of antiseptic solution, needles, needle guides, syringes, and other accessories, intended for use with an anesthetic drug. This device is used to administer regional blocks (e.g., paracervical, uterosacral, and pudendal) that may be used during labor, delivery, or both.
L.5200	Hemorrhoid prevention pressure wedge	2	A hemorrhoid prevention pressure wedge provides mechanical support to the perianal region during the labor and delivery process. External mechanical support of the perianal region is intended to help prevent the occurrence of external hemorrhoids associated with vaginal childbirth. Classification. Class II
L.5210	Pressure wedge for the reduction of cesarean delivery	2	A pressure wedge for the reduction of cesarean delivery is a prescription device that provides external mechanical support to the perianal region during the labor and vaginal delivery process. External mechanical support of the perianal region is intended to help reduce the occurrence of cesarean delivery.
L.5225	Abdominal decompression chamber	3	An abdominal decompression chamber is a hoodlike device used to reduce pressure on the pregnant patient's abdomen for the relief of abdominal pain during pregnancy or labor.
L.5250	Cervical cap	2	A cervical cap is a flexible cuplike receptacle that fits over the cervix to collect menstrual flow or to aid artificial insemination. This generic type of device is not for contraceptive use.
L.5300	Condom	2	A condom is a sheath which completely covers the penis with a closely fitting membrane. The condom is used for contraceptive and for prophylactic purposes (preventing transmission of sexually transmitted infections). The device may also be used to collect semen to aid in the diagnosis of infertility. The device may contain lubricants compatible for use with condoms.

L.5310	Condom with spermicidal lubricant	2	A condom with spermicidal lubricant is a sheath which completely covers the penis with a closely fitting membrane with a lubricant that contains a spermicidal agent, nonoxynol-9. This condom is used for contraceptive and prophylactic purposes (preventing sexually-transmitted diseases).
L.5320	Glans sheath	3	A glans sheath device is a sheath which covers only the glans penis or part thereof and may also cover the area in the immediate proximity thereof, the corona and frenulum, but not the entire shaft of the penis. It is indicated only for the prevention of pregnancy and not for the prevention of sexually-transmitted diseases.
L.5330	Multiple-use female	3	A multiple-use female condom is a sheath-like device that lines the vaginal wall and is inserted into the vagina prior to the initiation of coitus. At the conclusion of coitus, the device can be reused. It is indicated for contraception and prophylactic (preventing the transmission of sexually transmitted infections) purposes.
L.5340	Single-use internal condom	2	A single-use internal condom is an over-the-counter sheath-like device that lines the vaginal or anal wall and is inserted into the vagina or anus prior to the initiation of coitus. At the conclusion of coitus, it is removed and discarded. It is indicated for contraception and/or prophylactic (preventing the transmission of sexually transmitted infections) purposes.
L.5350	Contraceptive diaphragm and accessories	2	A contraceptive diaphragm is a closely fitting membrane placed between the posterior aspect of the pubic bone and the posterior vaginal fornix. The device covers the cervix completely and is used with a spermicide to prevent pregnancy. This generic type of device may include an introducer.
L.5360	Contraceptive intrauterine device (IUD) and introducer	3	A contraceptive intrauterine device (IUD) is a device used to prevent pregnancy. The device is placed high in the uterine fundus with a string extending from the device through the cervical os into the vagina. This generic type of device includes the introducer, but does not include contraceptive IUD's that function by drug activity, which are subject to the new drug provisions of the Federal Food, Drug, and Cosmetic Act (see 310.502).
L.5380	Contraceptive tubal occlusion device (TOD) and introducer	3	A contraceptive tubal occlusion device (TOD) and introducer is a device designed to close a fallopian tube with a mechanical structure, e.g., a band or clip on the outside of the fallopian tube or a plug or valve on the inside. The devices are used to prevent pregnancy.
L.5390	Perineal heater	2	A perineal heater is a device designed to apply heat directly by contact, or indirectly from a radiant source, to the surface of the perineum (the area between the vulva and the anus) and is used to soothe or to help heal the perineum after an episiotomy (incision of the vulvar orifice for obstetrical purposes).
L.5400	Menstrual cup	2	A menstrual cup is a receptacle placed in the vagina to collect menstrual flow.

L.5460	Scented or scented deodorized menstrual tampon	2	A scented or scented deodorized menstrual tampon is a device that is a plug made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge. It has scent (i.e., fragrance materials) added for aesthetic purposes (scented menstrual tampon) or for deodorizing purposes (scented deodorized menstrual tampon). This generic type of device does not include menstrual tampons treated with added antimicrobial agents or other drugs.
L.5470	Unscented menstrual tampon	2	An unscented menstrual tampon is a device that is a plug made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge. This generic type of device does not include menstrual tampons treated with scent (i.e., fragrance materials) or those with added antimicrobial agents or other drugs.
L.5900	Therapeutic vaginal douche apparatus	1,2	Identification: A therapeutic vaginal douche apparatus is a device that is a bag or bottle with tubing and a nozzle. The apparatus does not include douche solutions. The apparatus is intended and labeled for use in the treatment of medical conditions except it is not for contraceptive use. After filling the therapeutic vaginal douche apparatus with a solution, the patient uses the device to direct a stream of solution into the vaginal cavity. Classification:(1) Class 2；(2) Class 1 devices operated by gravity.
L.5920	Vaginal insufflator	1	A vaginal insufflator is a device used to treat vaginitis by introducing medicated powder from a hand-held bulb into the vagina through an open speculum.
L.5940	Powered vaginal muscle stimulator for therapeutic use	3	A powered vaginal muscle stimulator is an electrically powered device designed to stimulate directly the muscles of the vagina with pulsating electrical current. This device is intended and labeled for therapeutic use in increasing muscular tone and strength in the treatment of sexual dysfunction. This generic type of device does not include devices used to treat urinary incontinence.
L.5960	Genital vibrator for therapeutic use	2	A genital vibrator for therapeutic use is an electrically operated device intended and labeled for therapeutic use in the treatment of sexual dysfunction or as an adjunct to Kegel's exercise (tightening of the muscles of the pelvic floor to increase muscle tone).
L.5970	Clitoral engorgement device	2	A clitoral engorgement device is designed to apply a vacuum to the clitoris. It is intended for use in the treatment of female sexual arousal disorder.
L.5980	Surgical mesh for transvaginal pelvic organ prolapse repair	3	Surgical mesh for transvaginal pelvic organ prolapse repair is a prescription device intended to reinforce soft tissue in the pelvic floor. This device is a porous implant that is made of synthetic material, non-synthetic material, or a combination of synthetic and non-synthetic materials.

L.6100	Assisted reproduction needles	2	Assisted reproduction needles are devices used in in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other assisted reproduction procedures to obtain gametes from the body or introduce gametes, zygote(s), preembryo(s) and/or embryo(s) into the body. This generic type of device may include a single or double lumen needle and component parts, including needle guides, such as those used with ultrasound.
L.6110	Assisted reproduction catheters	2	Assisted reproduction catheters are devices used in in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other assisted reproduction procedures to introduce or remove gametes, zygote(s), preembryo(s), and/or embryo(s) into or from the body. This generic type of device may include catheters, cannulae, introducers, dilators, sheaths, stylets, and component parts.
L.6120	Assisted reproduction accessories	2	Assisted reproduction accessories are a group of devices used during assisted reproduction procedures, in conjunction with assisted reproduction needles and/or assisted reproduction catheters, to aspirate, incubate, infuse, and/or maintain temperature. This generic type of device may include: (1) Powered aspiration pumps used to provide low flow, intermittent vacuum for the aspiration of eggs (ova). (2) Syringe pumps (powered or manual) used to activate a syringe to infuse or aspirate small volumes of fluid during assisted reproduction procedures. (3) Collection tube warmers, used to maintain the temperature of egg (oocyte) collection tubes at or near body temperature. A dish/plate/microscope stage warmer is a device used to maintain the temperature of the egg (oocyte) during manipulation. (4) Embryo incubators, used to store and preserve gametes and/or embryos at or near body temperature. (5) Cryopreservation instrumentation and devices, used to contain, freeze, and maintain gametes and/or embryos at an appropriate freezing temperature.
L.6130	Assisted reproduction microtools	2	Assisted reproduction microtools are pipettes or other devices used in the laboratory to denude, micromanipulate, hold, or transfer human gametes or embryos for assisted hatching, intracytoplasmic sperm injection (ICSI), or other assisted reproduction methods.
L.6140	Assisted reproduction micropipette fabrication instruments	2	Assisted reproduction micropipette fabrication devices are instruments intended to pull, bevel, or forge a micropipette or needle for intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF) or other similar assisted reproduction procedures.
L.6150	Assisted reproduction micromanipulators and microinjectors	2	Assisted reproduction micromanipulators are devices intended to control the position of an assisted reproduction microtool. Assisted reproduction microinjectors are any device intended to control aspiration or expulsion of the contents of an assisted reproduction microtool.

L.6160	Assisted reproduction labware	2	Assisted reproduction labware consists of laboratory equipment or supplies intended to prepare, store, manipulate, or transfer human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other assisted reproduction procedures. These include syringes, IVF tissue culture dishes, IVF tissue culture plates, pipette tips, dishes, plates, and other vessels that come into physical contact with gametes, embryos or tissue culture media.
L.6165	Intravaginal culture system	2	An intravaginal culture system is a prescription device intended for preparing, holding, and transferring human gametes or embryos during intravaginal in vitro fertilization or intravaginal culture procedures.
L.6170	Assisted reproduction water and water purification systems	2	Assisted reproduction water purification systems are devices specifically intended to generate high quality, sterile, pyrogen-free water for reconstitution of media used for aspiration, incubation, transfer or storage of gametes or embryos for in vitro fertilization (IVF) or other assisted reproduction procedures. These devices may also be intended as the final rinse for labware or other assisted reproduction devices that will contact the gametes or embryos. These devices also include bottled water ready for reconstitution available from a vendor that is specifically intended for reconstitution of media used for aspiration, incubation, transfer, or storage of gametes or embryos for IVF or other assisted reproduction procedures.
L.6180	Reproductive media and supplements	2	Reproductive media and supplement are products that are used for assisted reproduction procedures. Media include liquid and powder versions of various substances that come in direct physical contact with human gametes or embryos (including water, acid solutions used to treat gametes or embryos, rinsing solutions, sperm separation media, supplements, or oil used to cover the media) for the purposes of preparation, maintenance, transfer or storage. Supplements are specific reagents added to media to enhance specific properties of the media (e.g., proteins, sera, antibiotics, etc.).
L.6190	Assisted reproductive microscopes and microscope accessories	1	Assisted reproduction microscopes and microscope accessories (excluding microscope stage warmers, which are classified under assisted reproduction accessories) are optical instruments used to enlarge images of gametes or embryos. Variations of microscopes and accessories used for these purposes would include phase contrast microscopes, dissecting microscopes and inverted stage microscopes.
L.6195	Assisted Reproduction Embryo Image Assessment System	2	An Assisted Reproduction Embryo Image Assessment System is a prescription device that is designed to obtain and analyze light microscopy images of developing embryos. This device provides information to aid in the selection of embryo(s) for transfer when there are multiple embryos deemed suitable for transfer or freezing.
L.6200	Assisted reproduction laser system	2	The assisted reproduction laser system is a device that images, targets, and controls the power and pulse duration of a laser beam used to ablate a small tangential hole in, or to thin, the zona pellucida of an embryo for assisted hatching or other assisted reproduction procedures.

L.9999	Others(Obstetrical and Gynecological Devices)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.
M.0001	Ophthalmic excimer laser system	3	Ophthalmic excimer laser system is intended for corneal ablation (i.e., photorefractive keratectomy) and other ophthalmologic procedures (e.g., surgical creation of a communication between the lacrimal sac and the nasal cavity). It includes a light source, controls/foot-switch, monitoring system, and probes.
M.0002	Endocapsular ring	3	An endocapsular ring is an ophthalmic device for placement into the capsular bag. It may be used for the stabilization of lens capsular bag when zonules are broken or missing. Examples are capsular tension rings.
M.0003	Lacrimal Punctum Plug	2	A lacrimal punctum plug is an ophthalmological device designed to be inserted through the punctal opening into the canaliculus in order to block tear drainage through the lacrimal drainage system.
M.1040	Ocular esthesiometer	1	An ocular esthesiometer is a device, such as a single-hair brush, intended to touch the cornea to assess corneal sensitivity.
M.1050	Adaptometer (biophotometer)	1	An adaptometer (biophotometer) is an AC-powered device that provides a stimulating light source which has various controlled intensities intended to measure the time required for retinal adaptation (regeneration of the visual purple) and the minimum light threshold.
M.1070	Anomaloscope	1	An anomaloscope is an AC-powered device intended to test for anomalies of color vision by displaying mixed spectral lines to be matched by the patient.
M.1090	Haidlinger brush	1	A Haidinger brush is an AC-powered device that provides two conical brushlike images with apexes touching which are viewed by the patient through a Nicol prism and intended to evaluate visual function. It may include a component for measuring macular integrity.
M.1120	Ophthalmic camera	2	An ophthalmic camera is an AC-powered device intended to take photographs of the eye and the surrounding area.
M.1140	Ophthalmic chair	1	An ophthalmic chair is an AC-powered or manual device with adjustable positioning in which a patient is to sit or recline during ophthalmological examination or treatment.
M.1160	Color vision plate illuminator	1	A color vision plate illuminator is an AC-powered device that is a lamp intended to properly illuminate color vision testing plates. It may include a filter.
M.1200	Optokinetic drum	1	An optokinetic drum is a drum-like device covered with alternating white and dark stripes or pictures that can be rotated on its handle. The device is intended to elicit and evaluate nystagmus (involuntary rapid movement of the eyeball) in patients.
M.1220	Corneal electrode	2	A corneal electrode is an AC-powered device, usually part of a special contact lens, intended to be applied directly to the cornea to provide data showing the changes in electrical potential in the retina after electroretinography (stimulation by light).

M.1250	Euthyscope	1,2	A euthyscope is a device that is a modified AC-powered or battery-powered ophthalmoscope (a perforated mirror device intended to inspect the interior of the eye) that projects a bright light encompassing an arc of about 30 degrees onto the fundus of the eye. The center of the light bundle is blocked by a black disk covering the fovea (the central depression of the macular retinae where only cones are present and blood vessels are lacking). The device is intended for use in the treatment of amblyopia (dimness of vision without apparent disease of the eye).
M.1270	Exophthalmometer	1	An exophthalmometer is a device, such as a ruler, gauge, or caliper, intended to measure the degree of exophthalmos (abnormal protrusion of the eyeball).
M.1290	Ophthalmic Fixation device	1	A fixation device is an AC-powered device intended for use as a fixation target for the patient during ophthalmological examination. The patient directs his or her gaze so that the visual image of the object falls on the fovea centralis (the center of the macular retina of the eye.)
M.1300	Afterimage flasher	2	An afterimage flasher is an AC-powered light that automatically switches on and off to allow performance of an afterimage test in which the patient indicates the positions of afterimages after the light is off. The device is intended to determine harmonious/anomalous retinal correspondence (the condition in which corresponding points on the retina have the same directional value).
M.1320	Fornixscope	1	A fornixscope is a device intended to pull back and hold open the eyelid to aid examination of the conjunctiva.
M.1340	Haploscope	1	A haploscope is an AC-powered device that consists of two movable viewing tubes, each containing a slide carrier, a low-intensity light source for the illumination of the slides, and a high-intensity light source for creating afterimages. The device is intended to measure strabismus (eye muscle imbalance), to assess binocular vision (use of both eyes to see), and to treat suppression and amblyopia (dimness of vision without any apparent disease of the eye).
M.1342	Strabismus detection device	2	A strabismus detection device is a prescription device designed to simultaneously illuminate both eyes with polarized light for automated detection of strabismus by analyzing foveal birefringence properties.
M.1350	Keratoscope	1	A keratoscope is an AC-powered or battery-powered device intended to measure and evaluate the corneal curvature of the eye. Lines and circles within the keratoscope are used to observe the corneal reflex. This generic type of device includes the photokeratoscope which records corneal curvature by taking photographs of the cornea.
M.1360	Visual field laser instrument	2	A visual field laser instrument is an AC-powered device intended to provide visible laser radiation that produces an interference pattern on the retina to evaluate retinal function.
M.1375	Bagolini lens	1	A Bagolini lens is a device that consists of a plane lens containing almost imperceptible striations that do not obscure visualization of objects. The device is placed in a trial frame and intended to determine harmonious/anomalous retinal correspondence (a condition in which corresponding points on the retina have the same directional values).

M.1380	Diagnostic condensing lens	1	A diagnostic condensing lens is a device used in binocular indirect ophthalmoscopy (a procedure that produces an inverted or reversed direct magnified image of the eye) intended to focus reflected light from the fundus of the eye.
M.1385	Polymethylmethacrylate (PMMA) diagnostic contact lens	2	A polymethylmethacrylate (PMMA) diagnostic contact lens is a device that is a curved shell of PMMA intended to be applied for a short period of time directly on the globe or cornea of the eye for diagnosis or therapy of intraocular abnormalities.
M.1390	Flexible diagnostic Fresnel lens	1	A flexible diagnostic Fresnel lens is a device that is a very thin lens which has its surface a concentric series of increasingly refractive zones. The device is intended to be applied to the back of the spectacle lenses of patients with aphakia (absence of the lens of the eye).
M.1395	Diagnostic Hruby fundus lens	1	A diagnostic Hruby fundus lens is a device that is a 55 diopter lens intended for use in the examination of the vitreous body and the fundus of the eye under slitlamp illumination and magnification.
M.1400	Maddox lens	1	A Maddox lens is a device that is a series of red cylinders that change the size, shape, and color of an image. The device is intended to be handheld or placed in a trial frame to evaluate eye muscle dysfunction.
M.1405	Ophthalmic trial lens set	1	An ophthalmic trial lens set is a device that is a set of lenses of various dioptric powers intended to be handheld or inserted in a trial frame for vision testing to determine refraction.
M.1410	Ophthalmic trial lens clip	1	An ophthalmic trial lens clip is a device intended to hold prisms, spheres, cylinders, or occluders on a trial frame or spectacles for vision testing.
M.1435	Maxwell spot	1	A Maxwell spot is an AC-powered device that is a light source with a red and blue filter intended to test macular function.
M.1450	Corneal radius measuring device	1	A corneal radius measuring device is an AC-powered device intended to measure corneal size by superimposing the image of the cornea on a scale at the focal length of the lens of a small, hand held, single tube penscope or eye gauge magnifier.
M.1460	Stereopsis measuring instrument	1	A stereopsis measuring instrument is a device intended to measure depth perception by illumination of objects placed on different planes.
M.1510	Eye movement monitor	2	An eye movement monitor is an AC-powered device with an electrode intended to measure and record ocular movements.
M.1570	Ophthalmoscope	2	An ophthalmoscope is an AC-powered or battery-powered device containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, and vitreous) and the retina of the eye.

M.1605	Perimeter	1	A perimeter is an AC-powered or manual device intended to determine the extent of the peripheral visual field of a patient. The device projects light on various points of a curved surface, and the patient indicates whether he or she sees the light.
M.1630	AC-powered photostimulator	2	An AC-powered photostimulator is an AC-powered device intended to provide light stimulus which allows measurement of retinal or visual function by perceptual or electrical methods (e.g., stroboscope).
M.1640	Ophthalmic preamplifier	2	An ophthalmic preamplifier is an AC-powered or battery-powered device intended to amplify electrical signals from the eye in electroretinography (recording retinal action currents from the surface of the eyeball after stimulation by light), electrooculography (testing for retinal dysfunction by comparing the standing potential in the front and the back of the eyeball), and electromyography (recording electrical currents generated in active muscle).
M.1650	Ophthalmic bar prism	1	An ophthalmic bar prism is a device that is a bar composed of fused prisms of gradually increasing strengths intended to measure latent and manifest strabismus (eye muscle deviation) or the power of fusion of a patient's eyes.
M.1655	Ophthalmic Fresnel prism	1	An ophthalmic Fresnel prism is a device that is a thin plastic sheet with embossed rulings which provides the optical effect of a prism. The device is intended to be applied to spectacle lenses to give a prismatic effect.
M.1660	Gonioscopic prism	1	A gonioscopic prism is a device that is a prism intended to be placed on the eye to study the anterior chamber. The device may have angled mirrors to facilitate visualization of anatomical features.
M.1665	Ophthalmic rotary prism	1	An ophthalmic rotary prism is a device with various prismatic powers intended to be handheld and used to measure ocular deviation in patients with latent or manifest strabismus (eye muscle deviation).
M.1670	Ophthalmic isotope uptake probe	2	An ophthalmic isotope uptake probe is an AC-powered device intended to measure, by a probe which is placed in close proximity to the eye, the uptake of a radioisotope (phosphorus 32) by tumors to detect tumor masses on, around, or within the eye.
M.1680	Ophthalmic projector	1	An ophthalmic projector is an AC-powered device intended to project an image on a screen for vision testing.
M.1690	Pupillograph	1	A pupillograph is an AC-powered device intended to measure the pupil of the eye by reflected light and record the responses of the pupil.
M.1700	Pupillometer	1	A pupillometer is an AC-powered or manual device intended to measure by reflected light the width or diameter of the pupil of the eye.
M.1750	Skiascopic rack	1	A skiascopic rack is a device that is a rack and a set of attached ophthalmic lenses of various dioptric strengths intended as an aid in refraction.

M.1760	Ophthalmic refractometer	1	An ophthalmic refractometer is an automatic AC-powered device that consists of a fixation system, a measurement and recording system, and an alignment system intended to measure the refractive power of the eye by measuring light reflexes from the retina.
M.1770	Manual refractor	1	A manual refractor is a device that is a set of lenses of varous dioptric powers intended to measure the refractive error of the eye.
M.1780	Retinoscope	1,2	A retinoscope is an AC-powered or battery-powered device intended to measure the refraction of the eye by illuminating the retina and noting the direction of movement of the light on the retinal surface and of the refraction by the eye of the emergent rays.
M.1790	Nearpoint ruler	1	A nearpoint ruler is a device calibrated in centimeters intended to measure the nearpoint of convergence (the point to which the visual lines are directed when convergence is at its maximum).
M.1800	Schirmer strip	1	A Schirmer strip is a device made of filter paper or similar material intended to be inserted under a patient's lower eyelid to stimulate and evaluate formation of tears.
M.1810	Tangent screen (campimeter)	1	A tangent screen (campimeter) is an AC-powered or battery-powered device that is a large square cloth chart with a central mark of fixation intended to map on a flat surface the central 30 degrees of a patient's visual field. This generic type of device includes projection tangent screens, target tangent screens and targets, felt tangent screens, and stereo campimeters.
M.1850	AC-powered slitlamp biomicroscope	2	An AC-powered slitlamp biomicroscope is an AC-powered device that is a microscope intended for use in eye examination that projects into a patient's eye through a control diaphragm a thin, intense beam of light.
M.1870	Stereoscope	1	A stereoscope is an AC-powered or battery-powered device that combines the images of two similar objects to produce a three-dimensional appearance of solidity and relief. It is intended to measure the angle of strabismus (eye muscle deviation), evaluate binocular vision (usage of both eyes to see), and guide a patient's corrective exercises of eye muscles.
M.1905	Nystagmus tape	1	Nystagmus tape is a device that is a long, narrow strip of fabric or other flexible material on which a series of objects are printed. The device is intended to be moved across a patient's field of vision to elicit optokinetic nystagmus (abnormal and irregular eye movements) and to test for blindness.
M.1910	Spectacle dissociation test system	1	A spectacle dissociation test system is an AC-powered or battery-powered device, such as a Lancaster test system, that consists of a light source and various filters, usually red or green filters, intended to subjectively measure imbalance of ocular muscles.
M.1925	Diurnal pattern recorder system	2	A diurnal pattern recorder system is a nonimplantable, prescription device incorporating a telemetric sensor to detect changes in ocular dimension for monitoring diurnal patterns of intraocular pressure (IOP) fluctuations.

M.1930	Tonometer and accessories	2	A tonometer and accessories is a manual device intended to measure intraocular pressure by applying a known force on the globe of the eye and measuring the amount of indentation produced (Schiotz type) or to measure intraocular tension by applanation (applying a small flat disk to the cornea). Accessories for the device may include a tonometer calibrator or a tonograph recording system. The device is intended for use in the diagnosis of glaucoma.
M.1945	Transilluminator	1,2	A transilluminator is an AC-powered or battery-powered device that is a light source intended to transmit light through tissues to aid examination of patients.
M.3100	Ophthalmic tantalum clip	2	An ophthalmic tantalum clip is a malleable metallic device intended to be implanted permanently or temporarily to bring together the edges of a wound to aid healing or prevent bleeding from small blood vessels in the eye.
M.3130	Ophthalmic conformer	1	An ophthalmic conformer is a device usually made of molded plastic intended to be inserted temporarily between the eyeball and eyelid to maintain space in the orbital cavity and prevent closure or adhesions during the healing process following surgery.
M.3200	Artificial eye	1	An artificial eye is a device resembling the anterior portion of the eye, usually made of glass or plastic, intended to be inserted in a patient's eye socket anterior to an orbital implant, or the eviscerated eyeball, for cosmetic purposes. The device is not intended to be implanted.
M.3300	Absorbable implant (scleral buckling method)	2	An absorbable implant (scleral buckling method) is a device intended to be implanted on the sclera to aid retinal reattachment.
M.3320	Eye sphere implant	2	An eye sphere implant is a device intended to be implanted in the eyeball to occupy space following the removal of the contents of the eyeball with the sclera left intact.
M.3340	Extraocular orbital implant	2	An extraocular orbital implant is a nonabsorbable device intended to be implanted during scleral surgery for buckling or building up the floor of the eye, usually in conjunction with retinal reattachment. Injectable substances are excluded.
M.3400	Keratoprosthesis	2	A keratoprosthesis is a device intended to provide a transparent optical pathway through an opacified cornea, either intraoperatively or permanently, in an eye that is not a reasonable candidate for a corneal transplant.
M.3600	Intraocular lens	3	An intraocular lens is a device made of materials such as glass or plastic intended to be implanted to replace the natural lens of an eye.
M.3800	Scleral shell	1	A scleral shell is a device made of glass or plastic that is intended to be inserted for short time periods over the cornea and proximal-cornea sclera for cosmetic or reconstructive purposes. An artificial eye is usually painted on the device. The device is not intended to be implanted.
M.3920	Eye valve implant	2	Eye valve implant is an implantable one-way pressure sensitive valve intended to reduce intraocular pressure in the anterior chamber of the eye. This device is for patients with glaucoma.

M.4070	Powered corneal burr	1	A powered corneal burr is an AC-powered or battery-powered device that is a motor and drilling tool intended to remove rust rings from the cornea of the eye.
M.4100	Radiofrequency electrosurgical cautery apparatus	2	A radiofrequency electrosurgical cautery apparatus is an AC-powered or battery-powered device intended for use during ocular surgery to coagulate tissue or arrest bleeding by a high frequency electric current.
M.4115	Thermal cautery unit	2	A thermal cautery unit is an AC-powered or battery-powered device intended for use during ocular surgery to coagulate tissue or arrest bleeding by heat conducted through a wire tip.
M.4150	Vitreous aspiration and cutting instrument	2	A vitreous aspiration and cutting instrument is an electrically powered device, which may use ultrasound, intended to remove vitreous matter from the vitreous cavity or remove a crystalline lens.
M.4155	Scleral plug	2	A scleral plug is a device intended to provide temporary closure of a scleral incision during an ophthalmic surgical procedure. These plugs prevent intraocular fluid and pressure loss when instruments are withdrawn from the eye. Scleral plugs include a head portion remaining above the sclera, which can be gripped for insertion and removal, and a shaft that fits inside the scleral incision. Scleral plugs are removed before completing the surgery.
M.4170	Cryophthalmic unit	2	A cryophthalmic unit is a device that is a probe with a small tip that becomes extremely cold through the controlled use of a refrigerant or gas. The device may be AC-powered. The device is intended to remove cataracts by the formation of an adherent ice ball in the lens, to freeze the eye and adjunct parts for surgical removal of scars, and to freeze tumors.
M.4250	Ophthalmic electrolysis unit	1,2	An ophthalmic electrolysis unit is an AC-powered or battery-powered device intended to destroy ocular hair follicles by applying a galvanic electrical current.
M.4270	Intraocular gas	3	An intraocular gas is a device consisting of a gaseous fluid intended to be introduced into the eye to place pressure on a detached retina.
M.4275	Intraocular fluid	3	An intraocular fluid is a device consisting of a nongaseous fluid intended to be introduced into the eye to aid performance of surgery, such as to maintain anterior chamber depth, preserve tissue integrity, protect tissue from surgical trauma, or function as a tamponade during retinal reattachment.
M.4280	Intraocular pressure measuring device	3	An intraocular pressure measuring device is a manual or AC-powered device intended to measure intraocular pressure. Also included are any devices found by FDA to be substantially equivalent to such devices. Accessories for the device may include calibrators or recorders. The device is intended for use in the diagnosis of glaucoma.
M.4300	Intraocular lens guide	1	An intraocular lens guide is a device intended to be inserted into the eye during surgery to direct the insertion of an intraocular lens and be removed after insertion is completed.
M.4335	Operating headlamp	1,2	An operating headlamp is an AC-powered or battery-powered device intended to be worn on the user's head to provide a light source to aid visualization during surgical, diagnostic, or therapeutic procedures.

M.4350	Manual ophthalmic surgical instrument	1	A manual ophthalmic surgical instrument is a nonpowered, handheld device intended to aid or perform ophthalmic surgical procedures. This generic type of device includes the manual corneal burr, ophthalmic caliper, ophthalmic cannula, eyelid clamp, ophthalmic muscle clamp, iris retractor clip, orbital compressor, ophthalmic curette, cystotome, orbital depressor, lachrymal dilator, erisophake, expressor, ophthalmic forcep, ophthalmic hook, sphere introducer, ophthalmic knife, ophthalmic suturing needle, lachrymal probe, trabeculotomy probe, cornea-sclera punch, ophthalmic retractor, ophthalmic ring (Flieringa), lachrymal sac rongeur, ophthalmic scissors, enucleating snare, ophthalmic spatula, ophthalmic specula, ophthalmic spoon, ophthalmic spud, trabeculotome or ophthalmic manual trephine.
M.4360	Ocular surgery irrigation device	1	An ocular surgery irrigation device is a device intended to be suspended over the ocular area during ophthalmic surgery to deliver continuous, controlled irrigation to the surgical field.
M.4370	Keratome	1	A keratome is an AC-powered or battery-powered device intended to shave tissue from sections of the cornea for a lamellar (partial thickness) transplant.
M.4390	Ophthalmic laser	2	An ophthalmic laser is an AC-powered device intended to coagulate or cut tissue of the eye, orbit, or surrounding skin by a laser beam.
M.4392	Nd:YAG laser for posterior capsulotomy	2	The Nd:YAG laser for posterior capsulotomy and peripheral iridotomy consists of a mode-locked or Q-switched solid state Nd:YAG laser intended for disruption of the posterior capsule or the iris via optical breakdown. The Nd:YAG laser generates short pulse, low energy, high power, coherent optical radiation. When the laser output is combined with focusing optics, the high irradiance at the target causes tissue disruption via optical breakdown. A visible aiming system is utilized to target the invisible Nd:YAG laser radiation on or in close proximity to the target tissue.
M.4400	Electronic metal locator	2	An electronic metal locator is an AC-powered device with probes intended to locate metallic foreign bodies in the eye or eye socket.
M.4570	Ophthalmic surgical marker	1	An ophthalmic surgical marker is a device intended to mark by use of ink, dye, or indentation the location of ocular or scleral surgical manipulation.
M.4610	Ocular pressure applicator	2	An ocular pressure applicator is a manual device that consists of a sphygmomanometer-type squeeze bulb, a dial indicator, a band, and bellows, intended to apply pressure on the eye in preparation for ophthalmic surgery.
M.4670	Phacofragmentation system	2	A phacofragmentation system is an AC-powered device with a fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract.
M.4690	Ophthalmic photocoagulator	2	An ophthalmic photocoagulator is an AC-powered device intended to use the energy from an extended noncoherent light source to occlude blood vessels of the retina, choroid, or iris.

M.4750	Ophthalmic eye shield	1	An ophthalmic eye shield is a device that consists of a plastic or aluminum eye covering intended to protect the eye or retain dressing materials in place.
M.4770	Ophthalmic operating spectacles (loupes)	1	Ophthalmic operating spectacles (loupes) are devices that consist of convex lenses or lens systems intended to be worn by a surgeon to magnify the surgical site during ophthalmic surgery.
M.4790	Ophthalmic sponge	2	An ophthalmic sponge is a device that is an absorbant sponge, pad, or spear made of folded gauze, cotton, cellulose, or other material intended to absorb fluids from the operative field in ophthalmic surgery.
M.5100	Ophthalmic beta radiation source	2	An ophthalmic beta radiation source is a device intended to apply superficial radiation to benign and malignant ocular growths.
M.5200	Eyelid thermal pulsation system	2	An eyelid thermal pulsation system is an electrically-powered device intended for use in the application of localized heat and pressure therapy to the eyelids. The device is used in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye. The system consists of a component that is inserted around the eyelids and a component to control the application of heat and pressure to the eyelids. Classification. Class II
M.5300	Tear electrostimulation device	2	A tear electrostimulation device is a non-implantable, electrostimulation device intended to increase tear production.
M.5310	Intranasal electrostimulation device for dry eye symptoms	2	An intranasal electrostimulation device for dry eye symptoms is a prescription non-implantable, electrostimulation device intended to increase tear production for improvement in dry eye symptoms.
M.5350	Ultrasound cyclodestructive device	2	Ultrasound cyclodestructive device is a device that reduces the intraocular pressure by generating a series of lesions caused by high-intensity focused ultrasound (HIFU) energy in the ciliary body and trabecular meshwork. This device is designed to treat refractory glaucoma.
M.5600	Ptosis crutch	1	A ptosis crutch is a device intended to be mounted on the spectacles of a patient who has ptosis (drooping of the upper eyelid as a result of faulty development or paralysis) to hold the upper eyelid open.
M.5700	Eyelid weight	2	An eyelid weight is a prescription device made of gold, tantalum, platinum, iridium, or surgical grade stainless steel that is rectangular in shape and contoured to the shape of the eye. The device is intended for the gravity assisted treatment of lagophthalmos (incomplete eyelid closure).
M.5838	Nasolacrimal compression device	1	A nasolacrimal compression device is a prescription device that is fitted to apply mechanical pressure to the nasal aspect of the orbital rim to reduce outflow through the nasolacrimal ducts.

M.5844	Corrective spectacle lens	1	A corrective spectacle lens is a glass or plastic device that is a lens intended to be worn by a patient in a spectacle frame to provide refractive corrections. The device may be modified to protect the eyes from bright sunlight (i.e., corrective sunglasses). Corrective sunglass lenses may be reflective, tinted, polarizing, or photosensitized. Products made with this corrective spectacle lens include corrective and protective sports goggles, such as swimmers' goggles, ski goggles, racquetball eye guards, and diving goggles.
M.5905	Oral electronic vision aid	2	An oral electronic vision aid is a battery-powered prescription device that contains an electrode stimulation array to generate electrotactile stimulation patterns that are derived from digital object images captured by a camera. It is intended to aid profoundly blind patients in orientation, mobility, and object recognition as an adjunctive device to other assistive methods such as a white cane or a guide dog.
M.5916	Rigid gas permeable contact lens	2,3	A rigid gas permeable contact lens is a device intended to be worn directly against the cornea of the eye to correct vision conditions. The device is made of various materials, such as cellulose acetate butyrate, polyacrylate-silicone, or silicone elastomers, whose main polymer molecules generally do not absorb or attract water.
M.5918	Rigid gas permeable contact lens care products	1,2	A rigid gas permeable contact lens care product is a device intended for use in the cleaning, conditioning, rinsing, lubricating/rewetting, or storing of a rigid gas permeable contact lens. This includes all solutions and tablets used together with rigid gas permeable contact lenses.Classification:(1)Class 1 contact lens container. ;(2)Class 2 other devices.
M.5925	Soft (hydrophilic) contact lens	2,3	A soft (hydrophilic) contact lens is a device intended to be worn directly against the cornea and adjacent limbal and scleral areas of the eye to correct vision conditions , act as a therapeutic bandage .The device is made of various polymer materials the main polymer molecules of which absorb or attract a certain volume (percentage) of water.The item includes plain soft (hydrophilic) contact lens.
M.5928	Soft (hydrophilic) contact lens care products	1,2	A soft (hydrophilic) contact lens care product is a device intended for use in the cleaning, rinsing, disinfecting, lubricating/rewetting, or storing of a soft (hydrophilic) contact lens. This includes all solutions and tablets used together with soft (hydrophilic) contact lenses and heat disinfecting units intended to disinfect a soft (hydrophilic) contact lens by means of heat. Classification:(1)Class 1 contact lens container. ;(2)Class 2 other devices.
M.9999	Others(Ophthalmic Devices)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.
N.0001	Orthopedic extracorporeal shock wave system	3	An orthopedic extracorporeal shock wave therapy system is a therapy system for orthopedic diseases. This device can be used only by health professionals.
N.0003	Intraarticular hyaluronic acid implants	3	Intra-articular hyaluronic acid implants are hyaluronic acid used for intra-articular injections.

N.0004	Inflatable bone expander system	2	An inflatable bone expander system is used to expand the vertebral body to form a cavity during vertebroplasty, so as to inject bone cement to restore and stabilize the vertebral body and can also be used for forming pores inside the cancellous bone of spine, hand, tibia, radius and calcaneus.
N.1100	Arthroscope	1,2	An arthroscope is an electrically powered endoscope intended to make visible the interior of a joint. The arthroscope and accessories also is intended to perform surgery within a joint.
N.1240	AC-powered dynamometer	2	An AC-powered dynamometer is an AC-powered device intended for medical purposes to assess neuromuscular function or degree of neuromuscular blockage by measuring, with a force transducer (a device that translates force into electrical impulses), the grip-strength of a patient's hand.
N.1250	Nonpowered dynamometer	1	A nonpowered dynamometer is a mechanical device intended for medical purposes to measure the pinch and grip muscle strength of a patient's hand.
N.1500	Goniometer	1,2	Identification: A goniometer is an AC-powered or battery powered device intended to evaluate joint function by measuring and recording ranges of motion, acceleration, or forces exerted by a joint. Classification: (1) Class 1 devices that does not use electrode lead wires and patient cables. ；(2) Class 2 devices that uses electrode lead wires and patient cables.
N.1520	Nonpowered goniometer	1	A nonpowered goniometer is a mechanical device intended for medical purposes to measure the range of motion of joints.
N.3000	Bone cap	1	A bone cap is a mushroom-shaped device intended to be implanted made of either silicone elastomer or ultra-high molecular weight polyethylene. It is used to cover the severed end of a long bone, such as the humerus or tibia, to control bone overgrowth in juvenile amputees.
N.3010	Bone fixation cerclage	2	A bone fixation cerclage is a device intended to be implanted that is made of alloys, such as cobalt-chromium-molybdenum, and that consists of a metallic ribbon or flat sheet or a wire. The device is wrapped around the shaft of a long bone, anchored to the bone with wire or screws, and used in the fixation of fractures.
N.3015	Bone heterograft	3	Bone heterograft is a device intended to be implanted that is made from mature (adult) bovine bones and used to replace human bone following surgery in the cervical region of the spinal column.
N.3020	Intramedullary fixation rod	2	An intramedullary fixation rod is a device intended to be implanted that consists of a rod made of alloys such as cobalt-chromium-molybdenum and stainless steel. It is inserted into the medullary (bone marrow) canal of long bones for the fixation of fractures.
N.3023	In vivo cured intramedullary fixation rod	2	An in vivo cured intramedullary fixation rod is a prescription implanted device consisting of a balloon that is inserted into the medullary canal of long bones for the fixation of fractures. The balloon is infused with, and completely encapsulates, a liquid monomer that is exposed to a curing agent which polymerizes the monomer within the balloon creating a hardened rigid structure.

N.3025	Passive tendon prosthesis	2	A passive tendon prosthesis is a device intended to be implanted made of silicon elastomer or a polyester reinforced medical grade silicone elastomer intended for use in the surgical reconstruction of a flexor tendon of the hand. The device is implanted for a period of 2 to 6 months to aid growth of a new tendon sheath. The device is not intended as a permanent implant nor to function as a replacement for the ligament or tendon nor to function as a scaffold for soft tissue ingrowth.
N.3027	Polymethylmethacrylate (PMMA) bone cement	2	Polymethylmethacrylate (PMMA) bone cement is a device intended to be implanted that is made from methylmethacrylate, polymethylmethacrylate, esters of methacrylic acid, or copolymers containing polymethylmethacrylate and polystyrene. The device is intended for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.
N.3030	Single/multiple component metallic bone fixation appliance and accessories	2	Single/multiple component metallic bone fixation appliances and accessories are devices intended to be implanted consisting of one or more metallic components and their metallic fasteners. The devices contain a plate, a nail/plate combination, or a blade/plate combination that are made of alloys, such as cobalt-chromium-molybdenum, stainless steel, and titanium, that are intended to be held in position with fasteners, such as screws and nails, or bolts, nuts, and washers. These devices are used for fixation of fractures of the proximal or distal end of long bones, such as intracapsular, intertrochanteric, intercervical, supracondylar, or condylar fractures of the femur; for fusion of a joint; or for surgical procedures that involve cutting a bone. The devices may be implanted or attached through the skin so that a pulling force (traction) may be applied to the skeletal system.
N.3040	Smooth or threaded metallic bone fixation fastener	2	A smooth or threaded metallic bone fixation fastener is a device intended to be implanted that consists of a stiff wire segment or rod made of alloys, such as cobalt-chromium-molybdenum and stainless steel, and that may be smooth on the outside, fully or partially threaded, straight or U-shaped; and may be either blunt pointed, sharp pointed, or have a formed, slotted head on the end. It may be used for fixation of bone fractures, for bone reconstructions, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.
N.3045	Resorbable calcium salt bone void filler device	2	A resorbable calcium salt bone void filler device is a resorbable implant intended to fill bony voids or gaps of the extremities, spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure.

N.3050	Spinal interlaminal fixation orthosis	2	A spinal interlaminal fixation orthosis is a device intended to be implanted made of an alloy, such as stainless steel, that consists of various hooks and a posteriorly placed compression or distraction rod. The device is implanted, usually across three adjacent vertebrae, to straighten and immobilize the spine to allow bone grafts to unite and fuse the vertebrae together. The device is used primarily in the treatment of scoliosis (a lateral curvature of the spine), but it also may be used in the treatment of fracture or dislocation of the spine, grades 3 and 4 of spondylolisthesis (a dislocation of the spinal column), and lower back syndrome.
N.3060	Spinal intervertebral body fixation orthosis	2	A spinal intervertebral body fixation orthosis is a device intended to be implanted made of titanium. It consists of various vertebral plates that are punched into each of a series of vertebral bodies. An eye-type screw is inserted in a hole in the center of each of the plates. A braided cable is threaded through each eye-type screw. The cable is tightened with a tension device and it is fastened or crimped at each eye-type screw. The device is used to apply force to a series of vertebrae to correct "sway back," scoliosis (lateral curvature of the spine), or other conditions.
N.3070	Pedicle screw spinal system	2,3	(a) Pedicle screw spinal systems are multiple component devices, made from a variety of materials, including alloys such as 316L stainless steel, 316LVM stainless steel, 22Cr-13Ni-5Mn stainless steel, Ti-6Al-4V, and unalloyed titanium, that allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such a spinal implant assembly consists of a combination of anchors (e.g., bolts, hooks, and/or screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and/or plate/rod combinations); and/or transverse connectors.(b) Classification: (1) Class 2 for devices that comply with the following listed special controls (comply with material standards, comply with mechanical testing standards, and comply with biocompatibility standards). (2) Class 3 for pedicle screw spinal systems intended for other purposes.
N.3080	Intervertebral body fusion device	2,3	An intervertebral body fusion device is an implanted single or multiple component spinal device made from a variety of materials, including titanium and polymers. The device is inserted into the intervertebral body space of the cervical or lumbosacral spine, and is intended for intervertebral body fusion.
N.3100	Ankle joint metal/composite semi-constrained cemented prosthesis	2	An ankle joint metal/composite semi-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits translation and rotation: in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component fabricated from ultra-high molecular weight polyethylene with carbon fibers composite, and is limited to those prostheses intended for use with bone cement (N.3027).

N.3110	Ankle joint metal/polymer semi-constrained cemented prosthesis	2	An ankle joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces and has no linkage across-the-joint. This generic type of device includes prostheses that have a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component made of ultra-high molecular weight polyethylene and is limited to those prostheses intended for use with bone cement (N.3027).
N.3120	Ankle joint metal/polymer non-constrained cemented prosthesis	3	An ankle joint metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a tibial component made of alloys, such as cobalt-chromium-molybdenum, and a talar component made of ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (888.3027).
N.3150	Elbow joint metal/metal or metal/polymer constrained cemented prosthesis	2	An elbow joint metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint. It is made of alloys, such as cobalt-chromium-molybdenum, or of these alloys and of an ultra-high molecular weight polyethylene bushing. The device prevents dislocation in more than one anatomic plane and consists of two components that are linked together. This generic type of device is limited to those prostheses intended for use with bone cement (888.3027).
N.3160	Elbow joint metal / polymer semi-constrained cemented prosthesis	2	An elbow joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a radial resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (888.3027).
N.3170	Elbow joint radial (hemi-elbow) polymer prosthesis	2	An elbow joint radial (hemi-elbow) polymer prosthesis is a device intended to be implanted made of medical grade silicone elastomer used to replace the proximal end of the radius.
N.3180	Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis	3	An elbow joint humeral (hemi-elbow) metallic uncemented prosthesis is a device intended to be implanted made of alloys, such as cobalt-chromium-molybdenum, that is used to replace the distal end of the humerus formed by the trochlea humeri and the capitulum humeri. The generic type of device is limited to prostheses intended for use without bone cement (888.3027).

N.3200	Finger joint metal / metal constrained uncemented prosthesis	3	A finger joint metal/metal constrained uncemented prosthesis is a device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane and consists of two components which are linked together. This generic type of device includes prostheses made of alloys, such as cobalt-chromium-molybdenum, or protheses made from alloys and ultra-high molecular weight polyethylene. This generic type of device is limited to prostheses intended for use without bone cement (888.3027).
N.3210	Finger joint metal / metal constrained cemented prosthesis	3	A finger joint metal/metal constrained cemented prosthesis is a device intended to be implanted to replace a metacarpophalangeal (finger) joint. This device prevents dislocation in more than one anatomic plane and has components which are linked together. This generic type of device includes prostheses that are made of alloys, such as cobalt-chromium-molybdenum, and is limited to those prostheses intended for use with bone cement (888.3027).
N.3220	Finger joint metal / polymer constrained cemented prosthesis	3	A finger joint metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane, and consists of two components which are linked together. This generic type of device includes prostheses that are made of alloys, such as cobalt-chromium-molybdenum, and ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (888.3027).
N.3230	Finger joint polymer constrained prosthesis	2	A finger joint polymer constrained prosthesis is a device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. This generic type of device includes prostheses that consist of a single flexible across-the-joint component made from either a silicone elastomer or a combination pf polypropylene and polyester material. The flexible across-the-joint component may be covered with a silicone rubber sleeve.
N.3300	Hip joint metal constrained cemented or uncemented prosthesis	3	A hip joint metal constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have components made of alloys, such as cobalt-chromium-molybdenum, and is intended for use with or without bone cement (888.3027). This device is not intended for biological fixation.
N.3310	Hip joint metal/polymer constrained cemented or uncemented prosthesis	2	A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high-molecular-weight polyethylene with or without a metal shell, made of alloys, such as cobalt-chromium-molybdenum and titanium alloys. This generic type of device is intended for use with or without bone cement (888.3027).

N.3320	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis	3	A hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis is a two-part device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those prostheses intended for use with bone cement (888.3027).
N.3330	Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis	3	A hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis is a two-part device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys, such as cobalt-chromium-molybdenum. The femoral component is intended to be fixed with bone cement. The acetabular component is intended for use without bone cement (888.3027).
N.3340	Hip joint metal/composite semi-constrained cemented prosthesis	2	A hip joint metal/composite semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high molecular weight polyethylene with carbon fibers composite. Both components are intended for use with bone cement (888.3027).
N.3350	Hip joint metal/polymer semi-constrained cemented prosthesis	2	A hip joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular resurfacing component made of ultra-high molecular weight polyethylene and is limited to those prostheses intended for use with bone cement (888.3027).

N.3353	Hip joint metal / ceramic / polymer semi-constrained cemented or nonporous uncemented prosthesis	2	A hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis is a device intended to be implanted to replace a hip joint. This device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. The two-part femoral component consists of a femoral stem made of alloys to be fixed in the intramedullary canal of the femur by impaction with or without use of bone cement. The proximal end of the femoral stem is tapered with a surface that ensures positive locking with the spherical ceramic (aluminium oxide, A1203) head of the femoral component. The acetabular component is made of ultra-high molecular weight polyethylene or ultra-high molecular weight polyethylene reinforced with nonporous metal alloys, and used with or without bone cement.
N.3358	Hip joint metal / polymer / metal semi-constrained porous-coated uncemented proshesis	2	A hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across the joint. This generic type of device has a femoral component made of a cobalt-chromium-molybdenum (Co-Cr-Mo) alloy or a titanium-aluminum-vanadium (Ti-6Al-4V) alloy and an acetabular component composed of an ultra-high molecular weight polyethylene articulating bearing surface fixed in a metal shell made of Co-Cr-Mo or Ti-6Al-4V. The femoral stem and acetabular shell have a porous coating made of, in the case of Co-Cr-Mo substrates, beads of the same alloy, and in the case of Ti-6Al-4V substrates, fibers of commercially pure titanium or Ti-6Al-4V alloy. The porous coating has a volume porosity between 30 and 70 percent, an average pore size between 100 and 1,000 microns, interconnecting porosity, and a porous coating thickness between 500 and 1,500 microns. The generic type of device has a design to achieve biological fixation to bone without the use of bone cement.
N.3360	Hip joint femoral(hemi-hip) metallic cemented or uncemented prosthesis	2	A hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis is a device intended to be implanted to replace a portion of the hip joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device includes designs which are intended to be fixed to the bone with bone cement (888.3027) as well as designs which have large window-like holes in the stem of the device and which are intended for use without bone cement. However, in these latter designs, fixation of the device is not achieved by means of bone ingrowth.
N.3370	Hip joint (hemi-hip) acetabular metal cemented prosthesis	3	A hip joint (hemi-hip) acetabular metal cemented prosthesis is a device intended to be implanted to replace a portion of the hip joint. This generic type of device includes prostheses that have an acetabular component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those prostheses intended for use with bone cement (888.3027).

N.3380	Hip joint femoral(hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis	3	A hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis is a two-part device intended to be implanted to replace the head and neck of the femur. This generic type of device includes prostheses that consist of a metallic stem made of alloys, such as cobalt-chromium-molybdenum, with an integrated cylindrical trunnion bearing at the upper end of the stem that fits into a recess in the head of the device. The head of the device is made of polyacetal (polyoxymethylene) and it is covered by a metallic alloy, such as cobalt-chromium-molybdenum. The trunnion bearing allows the head of the device to rotate on its stem. The prosthesis is intended for use with bone cement (888.3027).
N.3390	Hip joint femoral(hemi-hip) metal/polymerl cemented or uncemented prosthesis	2	A hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis is a two-part device intended to be implanted to replace the head and neck of the femur. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a snap-fit acetabular component made of an alloy, such as cobalt-chromium-molybdenum, and ultra-high molecular weight polyethylene. This generic type of device may be fixed to the bone with bone cement (888.3027) or implanted by impaction.
N.3400	Hip joint femoral(hemi-hip) metallic resurfacing prosthesis	2	A hip joint femoral (hemi-hip) metallic resurfacing prosthesis is a device intended to be implanted to replace a portion of the hip joint. This generic type of device includes prostheses that have a femoral resurfacing component made of alloys, such as cobalt-chromium-molybdenum.
N.3410	Hip joint metal/polymer semi-constrained resurfacing cemented prosthesis	3	A hip joint metal/polymer or ceramic/polymer semi-constrained resurfacing cemented prosthesis is a two-part device intended to be implanted to replace the articulating surfaces of the hip while preserving the femoral head and neck. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across the joint. This generic type of device includes prostheses that consist of a femoral cap component made of a metal alloy, such as cobalt-chromium-molybdenum, or a ceramic material, that is placed over a surgically prepared femoral head, and an acetabular resurfacing polymer component. Both components are intended for use with bone cement (888.3027).
N.3480	Knee joint femorotibial metallic constrained cemented prosthesis	3	A knee joint femorotibial metallic constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. The only knee joint movement allowed by the device is in the sagittal plane. This generic type of device includes prostheses that have an intramedullary stem at both the proximal and distal locations. The upper and lower components may be joined either by a solid bolt or pin, an internally threaded bolt with locking screw, or a bolt retained by circlip. The components of the device are made of alloys, such as cobalt-chromium-molybdenum. The stems of the device may be perforated, but are intended for use with bone cement (888.3027).

N.3490	Knee joint femorotibial metal/composite non-constrained cemented prosthesis	2	A knee joint femorotibial metal/composite non-constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as cobalt-chromium-molybdenum, and a tibial condylar component or components made of ultra-high molecular weight polyethylene with carbon fibers composite and are intended for use with bone cement (888.3027).
N.3500	Knee joint femorotibial metal/composite semi-constrained cemented prosthesis	2	A knee joint femorotibial metal/composite semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component with the articulating surfaces made of ultra-high molecular weight polyethylene with carbon-fibers composite and is limited to those prostheses intended for use with bone cement (888.3027).
N.3510	Knee joint femorotibial metal/polymer constrained cemented prosthesis	2	A knee joint femorotibial metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits translation or rotation in one or more planes and has components that are linked together or affined. This generic type of device includes prostheses composed of a ball-and-socket joint located between a stemmed femoral and a stemmed tibial component and a runner and track joint between each pair of femoral and tibial condyles. The ball-and-socket joint is composed of a ball at the head of a column rising from the stemmed tibial component. The ball, the column, the tibial plateau, and the stem for fixation of the tibial component are made of an alloy, such as cobalt-chromium-molybdenum. The ball of the tibial component is held within the socket of the femoral component by the femoral component's flat outer surface. The flat outer surface of the tibial component abuts both a reciprocal flat surface within the cavity of the femoral component and flanges on the femoral component designed to prevent distal displacement. The stem of the femoral component is made of an alloy, such as cobalt-chromium-moly- bdenum, but the socket of the component is made of ultra-high molecular weight polyethy- lene. The femoral component has metallic runners which align with the ultra-high molecular weight polyethylene tracks that press-fit into the metallic tibial component. The generic class also includes devices whose upper and lower components are linked with a solid bolt passing through a journal bearing of greater radius, permitting some rotation in the transverse plane, a minimal arc of abduction/adduction. This generic type of device is limited to those prostheses intended for use with bone cement (888.3027).

N.3520	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis	2	A knee joint femorotibial metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components made of ultra-high molecular weight polyethylene and are intended for use with bone cement (888.3027).
N.3530	Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis	2	A knee joint femorotibial metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component made of ultra-high molecular weight polyethylene and is limited to those prostheses intended for use with bone cement (888.3027).
N.3535	Knee joint femorotibial unicompartmental mental/polymer porous-coated uncemented prosthesis	2	A knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surface. It has no linkage across-the-joint. This generic type of device is designed to achieve biological fixation to bone without the use of bone cement. This identification includes fixed-bearing knee prostheses where the ultra-high molecular weight polyethylene tibial bearing is rigidly secured to the metal tibial baseplate.
N.3540	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis	2	A knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace part of a knee joint in the treatment of primary patellofemoral arthritis or chondromalacia. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes a component made of alloys, such as cobalt-chromium-molybdenum or austenitic steel, for resurfacing the intercondylar groove (femoral sulcus) on the anterior aspect of the distal femur, and a patellar component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for use with bone cement (888.3027). The patellar component is designed to be implanted only with its femoral component.

N.3550	Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis	3	A knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis is a device intended to be implanted to replace a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component, a tibial component, a cylindrical bolt and accompanying locking hardware that are all made of alloys, such as cobalt-chromium-molybdenum, and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. The retropatellar surfacing component may be attached to the resected patella either with a metallic screw or bone cement. All stemmed metallic components within this generic type are intended for use with bone cement (888.3027).
N.3560	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis	2	A knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (888.3027).
N.3565	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis	2	A knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis is a device intended to be implanted to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device is designed to achieve biological fixation to bone without the use of bone cement. This identification includes fixed-bearing knee prostheses where the ultra high molecular weight polyethylene tibial bearing is rigidly secured to the metal tibial base plate.
N.3570	Knee joint femoral (hemi-knee) metallic uncemented prosthesis	3	A knee joint femoral (hemi-knee) metallic uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum, intended to be implanted to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component with or without protuberance(s) for the enhancement of fixation and is limited to those prostheses intended for use without bone cement (888.3027).

N.3580	Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis	2,3	A knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum, intended to be implanted to replace the retropatellar articular surface of the patellofemoral joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a retropatellar resurfacing component and an orthopedic screw to transfix the patellar remnant. This generic type of device is limited to those prostheses intended for use without bone cement (888.3027).
N.3590	Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis	2	A knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This prosthesis is made of alloys, such as cobalt-chromium-molybdenum, and is intended to resurface one tibial condyle. The generic type of device is limited to those prostheses intended for use without bone cement (888.3027).
N.3640	Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis	3	A shoulder joint metal/metal or metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid component made of this alloy or a combination of this alloy and ultra-high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (888.3027).
N.3650	Shoulder joint metal / polymer non-constrained cemented prosthesis	2	A shoulder joint metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (888.3027).
N.3660	Shoulder joint metal/polymer semi-constrained cemented prosthesis	2	A shoulder joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (888.3027).

N.3670	Shoulder joint metal/polymer/metal nonconstrained or semiconstrained porous-coated uncemented prosthesis	2	A shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits movement in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys such as cobalt-chromium-molybdenum (Co-Cr-Mo) and titanium-aluminum-vanadium (Ti-6Al-4V) alloys, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, or a combination of an articulating ultra-high molecular weight bearing surface fixed in a metal shell made of alloys such as Co-Cr-Mo and Ti-6Al-4V. The humeral component and glenoid backing have a porous coating made of, in the case of Co-Cr-Mo components, beads of the same alloy or commercially pure titanium powder, and in the case of Ti-6Al-4V components, beads or fibers of commercially pure titanium or Ti-6Al-4V alloy, or commercially pure titanium powder. The porous coating has a volume porosity between 30 and 70 percent, an average pore size between 100 and 1,000 microns, interconnecting porosity, and a porous coating thickness between 500 and 1,500 microns. This generic type of device is designed to achieve biological fixation to bone without the use of bone cement.
N.3680	Shoulder joint glenoid (hemi-shoulder)metallic cemented prosthesis	3	A shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis is a device that has a glenoid (socket) component made of alloys, such as cobalt-chromium-molybdenum, or alloys with ultra-high molecular weight polyethylene and intended to be implanted to replace part of a shoulder joint. This generic type of device is limited to those prostheses intended for use with bone cement (888.3027).
N.3690	Shoulder joint humeral (hemi-shoulder)metallic uncemented prosthesis	2	A shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum. It has an intramedullary stem and is intended to be implanted to replace the articular surface of the proximal end of the humerus and to be fixed without bone cement (888.3027). This device is not intended for biological fixation.
N.3720	Toe joint polymer constrained prosthesis	2	A toe joint polymer constrained prosthesis is a device made of silicone elastomer or polyester reinforced silicone elastomer intended to be implanted to replace the first metatarsophalangeal (big toe) joint. This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.
N.3730	Toe joint phalangeal (hemi-toe)polymer prosthesis	2	A toe joint phalangeal (hemi-toe) polymer prosthesis is a device made of silicone elastomer intended to be implanted to replace the base of the proximal phalanx of the toe.
N.3750	Wrist joint carpal lunate polymer prosthesis	2	A wrist joint carpal lunate prosthesis is a one-piece device made of silicone elastomer intended to be implanted to replace the carpal lunate bone of the wrist.
N.3760	Wrist joint carpal scaphoid polymer prosthesis	2	A wrist joint carpal scaphoid polymer prosthesis is a one-piece device made of silicone elastomer intended to be implanted to replace the carpal scaphoid bone of the wrist.

N.3770	Wrist joint carpal trapezium polymer prosthesis	2	A wrist joint carpal trapezium polymer prosthesis is a one-piece device made of silicone elastomer or silicone elastomer/polyester material intended to be implanted to replace the carpal trapezium bone of the wrist.
N.3780	Wrist joint polymer constrained prosthesis	2	A wrist joint polymer constrained prosthesis is a device made of polyester-reinforced silicone elastomer intended to be implanted to replace a wrist joint. This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.
N.3790	Wrist joint metal constrained cemented prosthesis	3	A wrist joint metal constrained cemented prosthesis is a device intended to be implanted to replace a wrist joint. The device prevents dislocation in more than one anatomic plane and consists of either a single flexible across-the-joint component or two components linked together. This generic type of device is limited to a device which is made of alloys, such as cobalt-chromium-molybdenum, and is limited to those prostheses intended for use with bone cement (888.3027).
N.3800	Wrist joint metal/polymer semi-constrained cemented prosthesis	2	A wrist joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a wrist joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have either a one-part radial component made of alloys, such as cobalt-chromium-molybdenum, with an ultra-high molecular weight polyethylene bearing surface, or a two-part radial component made of alloys and an ultra-high molecular weight polyethylene ball that is mounted on the radial component with a trunnion bearing. The metallic portion of the two-part radial component is inserted into the radius. These devices have a metacarpal component(s) made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those prostheses intended for use with bone cement (888.3027).
N.3810	Wrist joint ulnar(hemi-wrist) polymer prosthesis	2	A wrist joint ulnar (hemi-wrist) polymer prosthesis is a mushroom-shaped device made of a medical grade silicone elastomer or ultra-high molecular weight polyethylene intended to be implanted into the intramedullary canal of the bone and held in place by a suture. Its purpose is to cover the resected end of the distal ulna to control bone overgrowth and to provide an articular surface for the radius and carpus.
N.4150	Calipers for clinical use	1	A caliper for clinical use is a compass-like device intended for use in measuring the thickness or diameter of a part of the body or the distance between two body surfaces, such as for measuring an excised skeletal specimen to determine the proper replacement size of a prosthesis.
N.4200	Cement dispenser	1	A cement dispenser is a nonpowered syringe-like device intended for use in placing bone cement (888.3027) into surgical sites.
N.4210	Cement mixer for clinical use	1	A cement mixer for clinical use is a device consisting of a container intended for use in mixing bone cement (888.3027).

N.4220	Cement monomer vapor evacuator	1	A cement monomer vapor evacuator is a device intended for use during surgery to contain or remove undesirable fumes, such as monomer vapor from bone cement (888.3027).
N.4230	Cement ventilation tube	1	A cement ventilation tube is a tube-like device usually made of plastic intended to be inserted into a surgical cavity to allow the release of air or fluid from the cavity as it is being filled with bone cement (888.3027).
N.4300	Depth gauge for clinical use	1	A depth gauge for clinical use is a measuring device intended for various medical purposes, such as to determine the proper length of screws for fastening the ends of a fractured bone.
N.4540	Orthopedic manual surgical instrument	1	An orthopedic manual surgical instrument is a nonpowered hand-held device intended for medical purposes to manipulate tissue, or for use with other devices in orthopedic surgery. This generic type of device includes the cerclage applier, awl, bender, drill brace, broach, burr, corkscrew, countersink, pin crimper, wire cutter, prosthesis driver, extractor, file, fork, needle holder, impactor, bending or contouring instrument, compression instrument, passer, socket positioner, probe, femoral neck punch, socket pusher, reamer, rongeur, scissors, screwdriver, bone skid, staple driver, bone screw starter, surgical stripper, tamp, bone tap, trephine, wire twister, and wrench.
N.4580	Sonic surgical instrument and accessories/attachments	2	A sonic surgical instrument is a hand-held device with various accessories or attachments, such as a cutting tip that vibrates at high frequencies, and is intended for medical purposes to cut bone or other materials, such as acrylic.
N.4600	Protractor for clinical use	1	A protractor for clinical use is a device intended for use in measuring the angles of bones, such as on x-rays or in surgery.
N.4800	Template for clinical use	1	A template for clinical use is a device that consists of a pattern or guide intended for medical purposes, such as selecting or positioning orthopedic implants or guiding the marking of tissue before cutting.
N.5850	Nonpowered orthopedic traction apparatus and accessories	1	A nonpowered orthopedic traction apparatus is a device that consists of a rigid frame with nonpowered traction accessories, such as cords, pulleys, or weights, and that is intended to apply a therapeutic pulling force to the skeletal system.
N.5890	Noninvasive traction component	1	A noninvasive traction component is a device, such as a head halter, pelvic belt, or a traction splint, that does not penetrate the skin and is intended to assist in connecting a patient to a traction apparatus so that a therapeutic pulling force may be applied to the patient's body.
N.5940	Cast component	1	A cast component is a device intended for medical purposes to protect or support a cast. This generic type of device includes the cast heel, toe cap, cast support, and walking iron.
N.5960	Cast removal instrument	1	A cast removal instrument is an AC-powered, hand-held device intended to remove a cast from a patient. This generic type of device includes the electric cast cutter and cast vacuum.

N.5980	Manual cast application and removal instrument	1	A manual cast application and removal instrument is a nonpowered hand-held device intended to be used in applying or removing a cast. This generic type of device includes the cast knife, cast spreader, plaster saw, plaster dispenser, and casting stand.
N.9999	Others(Orthopedic Devices)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.
O.0001	Static electric therapy apparatus	2	A static electric therapy apparatus is a device applying electrical field to human body and intended to relieve shoulder stiffness, headache, and chronic constipation. This type of device generally contains voltage transformer circuit, safety circuit, rectification circuit, electrodes, and insulators. The device uses safety circuit to limit its output current and creates a voltage of approximately 600 to 10,000 volts.
O.0002	Non-invasive bone growth stimulator	3	The non-invasive bone growth stimulator is a non-invasive device used to promote bone growth. This device can use magnetic fields or other working principle to stimulate fracture bones to accelerate healing.
O.0003	Topical refrigerant	1	Topical refrigerant is the non-medicated spray used to rapid cooling of skin.
O.0005	Optical position/movement recording system	2	An optical position/movement recording system is a device that monitors the movement of a patient's body. The device assists a patient for rehabilitation and provides the information to health professionals for evaluating the rehabilitation status of a patient.
O.0006	Continuous Passive Motion Device	1	Continuous passive motion device is to move a specific joint of the patient through the designed range of motions without applying force. This device aids patients, who suffer joint replacement surgery or with neurological disease, to increase the range of joint motion.
O.1175	Electrode cable	1	An electrode cable is a device composed of strands of insulated electrical conductors laid together around a central core and intended for medical purposes to connect an electrode from a patient to a diagnostic machine.
O.1225	Chronaximeter	2	A chronaximeter is a device intended for medical purposes to measure neuromuscular excitability by means of a strength-duration curve that provides a basis for diagnosis and prognosis of neurological dysfunction.
O.1375	Diagnostic electromyograph	2	A diagnostic electromyograph is a device intended for medical purposes, such as to monitor and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor and display the electrical activity produced by nerves, for the diagnosis and prognosis of neuromuscular disease.
O.1385	Diagnostic electromyograph needle electrode	2	A diagnostic electromyograph needle electrode is a monopolar or bipolar needle intended to be inserted into muscle or nerve tissue to sense bioelectrical signals. The device is intended for medical purposes for use in connection with electromyography (recording the intrinsic electrical properties of skeletal muscle).
O.1450	Powered reflex hammer	2	A powered reflex hammer is a motorized device intended for medical purposes to elicit and determine controlled deep tendon reflexes.

O.1575	Force-measuring platform	1	A force-measuring platform is a device intended for medical purposes that converts pressure applied upon a planar surface into analog mechanical or electrical signals. This device is used to determine ground reaction force, centers of percussion, centers of torque, and their variations in both magnitude and direction with time.
O.1600	Intermittent pressure measurement system	1	An intermittent pressure measurement system is an evaluative device intended for medical purposes, such as to measure the actual pressure between the body surface and the supporting media.
O.1615	Miniature pressure transducer	1	A miniature pressure transducer is a device intended for medical purposes to measure the pressure between a device and soft tissue by converting mechanical inputs to analog electrical signals.
O.1850	Diagnostic muscle stimulator	2	A diagnostic muscle stimulator is a device used mainly with an electromyograph machine to initiate muscle activity. It is intended for medical purposes, such as to diagnose motor nerve or sensory neuromuscular disorders and neuromuscular function.
O.1925	Isokinetic Testing and Evaluation System	1	An isokinetic testing and evaluation system is a rehabilitative exercise device intended for medical purposes, such as to measure, evaluate, and increase the strength of muscles and the range of motion of joints.
O.3025	Prosthetic and orthotic accessory	1	A prosthetic and orthotic accessory is a device intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis. Examples of prosthetic and orthotic accessories include the following: A pelvic support band and belt, a cast shoe, a cast bandage, a limb cover, a prosthesis alignment device, a postsurgical pylon, a transverse rotator, and a temporary training splint.
O.3075	Cane	1	A cane is a device intended for medical purposes that is used to provide minimal weight support while walking. Examples of canes include the following: A standard cane, a forearm cane, and a cane with a tripod, quad, or retractable stud on the ground end.
O.3100	Mechanical chair	1	A mechanical chair is a manually operated device intended for medical purposes that is used to assist a disabled person in performing an activity that the person would otherwise find difficult to do or be unable to do. Examples of mechanical chairs include the following: A chair with an elevating seat used to raise a person from a sitting position to a standing position and a chair with casters used by a person to move from one place to another while sitting.
O.3110	Electric positioning chair	2	An electric positioning chair is a device with a motorized positioning control that is intended for medical purposes and that can be adjusted to various positions. The device is used to provide stability for patients with athetosis (involuntary spasms) and to alter postural positions.
O.3150	Crutch	1	A crutch is a device intended for medical purposes for use by disabled persons to provide minimal to moderate weight support while walking.

O.3175	Flotation cushion	1	A flotation cushion is a device intended for medical purposes that is made of plastic, rubber, or other type of covering, that is filled with water, air, gel, mud, or any other substance allowing a flotation media, used on a seat to lessen the likelihood of skin ulcers.
O.3410	External limb orthotic component	1	An external limb orthotic component is a device intended for medical purposes for use in conjunction with an orthosis (brace) to increase the function of the orthosis for a patient's particular needs. Examples of external limb orthotic components include the following: A brace-setting twister and an external brace stirrup.
O.3420	External limb prosthetic component	1	An external limb prosthetic component is a device intended for medical purposes that, when put together with other appropriate components, constitutes a total prosthesis. Examples of external limb prosthetic components include the following: Ankle, foot, hip, knee, and socket components; mechanical or powered hand, hook, wrist unit, elbow joint, and shoulder joint components; and cable and prosthesis suction valves.
O.3450	Upper extremity prosthesis	2	An upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components, is a prescription device intended for medical purposes, and is intended to replace a partially or fully amputated or congenitally absent upper extremity. It uses electronic inputs (other than simple, manually controlled electrical components such as switches) to provide greater than two independent and simultaneously powered degrees of freedom and includes a simultaneously powered elbow and/or shoulder. Prosthetic arm components that are intended to be used as a system with other arm components must include all degrees of freedom of the total upper extremity prosthesis system.
O.3475	Limb orthosis	1	A limb orthosis (brace) is a device intended for medical purposes that is worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement. Examples of limb orthoses include the following: A whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.
O.3480	Powered lower extremity exoskeleton	2	A powered lower extremity exoskeleton is a prescription device that is composed of an external, powered, motorized orthosis that is placed over a person's paralyzed or weakened limbs for medical purposes.
O.3490	Truncal orthosis	1	A truncal orthosis is a device intended for medical purposes to support or to immobilize fractures, strains, or sprains of the neck or trunk of the body. Examples of truncal orthoses are the following: Abdominal, cervical, cervical-thoracic, lumbar, lumbo-sacral, rib fracture, sacroiliac, and thoracic orthoses and clavicle splints.
O.3500	External assembled lower limb prosthesis	1	An external assembled lower limb prosthesis is a device that is intended for medical purposes and is a preassembled external artificial limb for the lower extremity. Examples of external assembled lower limb prostheses are the following: Knee/shank/ankle/foot assembly and thigh/knee/shank/ankle/foot assembly.

O.3520	Plinth	1	A plinth is a flat, padded board with legs that is intended for medical purposes. A patient is placed on the device for treatment or examination.
O.3610	Rigid pneumatic structure orthosis	3	A rigid pneumatic structure orthosis is a device intended for medical purposes to provide whole body support by means of a pressurized suit to help thoracic paraplegics walk.
O.3640	Arm sling	1	An arm sling is a device intended for medical purposes to immobilize the arm, by means of a fabric band suspended from around the neck.
O.3665	Congenital hip dislocation abduction splint	1	A congenital hip dislocation abduction splint is a device intended for medical purposes to stabilize the hips of a young child with dislocated hips in an abducted position (away from the midline).
O.3675	Denis Brown splint	1	A Denis Brown splint is a device intended for medical purposes to immobilize the foot. It is used on young children with tibial torsion (excessive rotation of the lower leg) or club foot.
O.3690	Powered wheeled stretcher	2	A powered wheeled stretcher is a battery-powered table with wheels that is intended for medical purposes for use by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods because of skin ulcers or contractures (muscle contractions).
O.3750	Mechanical table	1	A mechanical table is a device intended for medical purposes that has a flat surface that can be inclined or adjusted to various positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.
O.3760	Powered table	1	A powered table is a device intended for medical purposes that is an electrically operated flat surface table that can be adjusted to various positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.
O.3800	Motorized vehicle for medical purposes	2	A motorized vehicle for medical purposes is a gasoline-fueled or battery-powered device intended for medical purposes that is used for transportation by mobility disabled persons. The maximum speed limit of motorized vehicles for medical purposes is 10 km/h.
O.3825	Mechanical walker	1	A mechanical walker is a four-legged device with a metal frame intended for medical purposes to provide moderate weight support while walking. It is used by disabled persons who lack strength, good balance, or endurance.
O.3850	Mechanical wheelchair	1	A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.Mechanical wheelchairs shall comply with the performance requirements of national standard CNS 14964-8, ISO 7176-8 or equivalent international standards.
O.3860	Powered wheelchair	2	A powered wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.The maximum speed limit of powered wheelchairs is 10 km/h. This classification contains external power components for use in mechanical wheelchairs

O.3880	Special grade wheelchair	2	A special grade wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. It is intended to be used in all environments for long-term use, e.g., for paraplegics, quadraplegics, and amputees.
O.3890	Stair-climbing wheelchair	2	A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device is intended to climb stairs.
O.3900	Standup wheelchair	2	A standup wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device incorporates an external manually controlled mechanical system that is intended to raise a paraplegic to an upright position by means of an elevating seat.
O.3930	Mobile wheelchair elevator	1,2	A wheelchair elevator is a motorized lift device intended for medical purposes.(a) Providing a means for a disabled person sitting on a wheelchair to move from one level to another. Classification: Class 2.(b) Devices that are operated by an accompany person. Classification: Class 1. The devices are required to meet the electrical safety standard (e.g. IEC 60601-1) and performance standard (e.g. ISO 7176-28 or the other equivalent international standards).
O.5100	Immersion hydrobath	2	An immersion hydrobath is a device intended for medical purposes that consists of water agitators and that may include a tub to be filled with water. The water temperature may be measured by a gauge. It is used in hydrotherapy to relieve pain and itching and as an aid in the healing process of inflamed and traumatized tissue, and it serves as a setting for removal of contaminated tissue.
O.5110	Paraffin bath	2	A paraffin bath is a device intended for medical purposes that consists of a tub to be filled with liquid paraffin (wax) and maintained at an elevated temperature in which the patient's appendages (e.g., hands or fingers) are placed to relieve pain and stiffness.
O.5125	Nonpowered sitz bath	1	A nonpowered sitz bath is a device intended for medical purposes that consists of a tub to be filled with water for use in external hydrotherapy to relieve pain or pruritis and to accelerate the healing of inflamed or traumatized tissues of the perianal and perineal areas.
O.5150	Powered patient transport	1,2	(a)A powered patient transport is a motorized device intended for medical purposes to assist transfers of patients to and from the bath, beds, chairs, treatment modalities, transport vehicles, and up and down flights of stairs. This generic type of device does not include motorized threewheeled vehicles or wheelchairs. Classification:Class 2. (b) Devices that are operated by an accompany person. Classification: Class 1. The devices are required to meet the electrical safety standard (e.g. IEC 60601-1) and performance standard (e.g. ISO 7176-28 or the other equivalent international standards).

O.5160	Air-fluidized bed	1	An air-fluidized bed is a device employing the circulation of filtered air through ceramic spherules (small, round ceramic objects) that is intended for medical purposes to treat or prevent bedsores, to treat severe or extensive burns, or to aid circulation.
O.5170	Powered flotation therapy bed	1	A powered flotation therapy bed is a device that is equipped with a mattress that contains a large volume of constantly moving water, air, mud, or sand. It is intended for medical purposes to treat or prevent a patient's bedsores, to treat severe or extensive burns, or to aid circulation. The mattress may be electrically heated.
O.5180	Manual patient rotation bed	1	A manual patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended for medical purposes to treat or prevent bedsores, to treat severe and extensive burns, or to aid circulation.
O.5225	Powered patient rotation bed	1	A powered patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended for medical purposes to treat or prevent bedsores, to treat severe and extensive burns, urinary tract blockage, and to aid circulation.
O.5250	Moist steam cabinet	2	A moist steam cabinet is a device intended for medical purposes that delivers a flow of heated, moisturized air to a patient in an enclosed unit. It is used to treat arthritis and fibrosis (a formation of fibrosis tissue) and to increase local blood flow.
O.5275	Microwave diathermy	2,3	(a)Microwave diathermy for use in applying therapeutic deep heat for selected medical conditions --(1)Identification. A microwave diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body electromagnetic energy in the microwave frequency bands of 915 megahertz to 2,450 megahertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies. (2)Classification: Class 2. (b)Microwave diathermy for all other uses --(1)Identification. A microwave diathermy for all other uses except for the treatment of malignancies is a device that applies to the body electromagnetic energy in the microwave frequency bands of 915 megahertz to 2,450 megahertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section. (2)Classification: Class 3.

O.5290	Shortwave diathermy	2,3	(a)Shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions --(1)Identification: A shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body electromagnetic energy in the radio frequency bands of 13 megahertz to 27.12 megahertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies. (2)Classification: Class 2. (b)Shortwave diathermy for all other uses --(1)Identification: A shortwave diathermy for all other uses except for the treatment of malignancies is a device that applies to the body electromagnetic energy in the radio frequency bands of 13 megahertz to 27.12 megahertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section. (2) Classification: Class 3.
O.5300	Ultrasonic diathermy	2,3	(a)Ultrasonic diathermy for use in applying therapeutic deep heat for selected medical conditions --(1)Identification: An ultrasonic diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies. (2) Classification: Class 2. (b)Ultrasonic diathermy for all other uses --(1)Identification: An ultrasonic diathermy for all other uses except for the treatment of malignancies is a device that applies to the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section. (2)Classification: Class 3.
O.5360	Measuring exercise equipment	2	Measuring exercise equipment consist of manual devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. These devices also include instrumentation, such as electrocardiograph, spirometer and sphygmomanometer, that provide information used for physical evaluation.
O.5500	Infrared lamp	2	An infrared lamp is a device intended for medical purposes that emits energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers) to provide topical heating.

O.5525	Iontophoresis device	2	(a) Iontophoresis device intended for certain specified uses - Identification: An iontophoresis device is intended for use in the diagnosis of cystic fibrosis or is used along with certain drugs to achieve specific functions. This device uses a current to introduce ions of soluble salts or certain drugs into the patient's body for inducing sweating. This device collects patient's sweat and determines its composition and weight to diagnose cystic fibrosis. Classification: Class 2. (b) Iontophoresis device intended for any other purposes - Identification: An iontophoresis device intended for certain specified uses other than those referred to in paragraph (a) above. This device uses a current to introduce ions of drugs or non-drug solutions into the patient's body for achieving specific medical purposes. Classification: Class 2.
O.5575	Powered external limb overload warning device	2	A powered external limb overload warning device is a device intended for medical purposes to warn a patient of an overload or an underload in the amount of pressure placed on a leg.
O.5650	Powered inflatable tube massager	2	A powered inflatable tube massager is a powered device intended for medical purposes, such as to relieve minor muscle aches and pains and to increase circulation. It simulates kneading and stroking of tissues with the hands by use of an inflatable pressure cuff.
O.5700	Cold pack	1	A cold pack is a device intended for medical purposes that consists of a compact fabric envelope containing a specially hydrated pliable silicate gel or a flexible bandage consists of non-medical liquid capable of forming to the contour of the body and that provides cold therapy for body surfaces.
O.5710	Hot or cold disposable pack	1	A hot or cold disposable pack is a device intended for medical purposes that consists of a sealed plastic bag incorporating chemicals that, upon activation, provides hot or cold therapy for body surfaces.
O.5720	Water circulating hot or cold pack	1	A water circulating hot or cold pack is a device intended for medical purposes that operates by pumping heated or chilled water through a plastic bag and that provides hot or cold therapy for body surfaces.
O.5730	Moist heat pack	1	A moist heat pack is a device intended for medical purposes that consists of silica gel in a fabric container used to retain an elevated temperature and that provides moist heat therapy for body surfaces.
O.5740	Powered heating pad	1	A powered heating pad is an electrical device intended for medical purposes that provides dry heat therapy for body surfaces. It is capable of maintaining an elevated temperature during use.
O.5760	Nonpowered lower extremity pressure wrap	1	A nonpowered lower extremity pressure wrap is a prescription device that applies mechanical pressure by wrapping around the lower extremity, such as the leg or foot, and is intended for primary Restless Leg Syndrome.
O.5765	Pressure-applying device	1	A presssure-applying device is a device intended for medical purposes to apply continuous pressure to the paravertebral tissues for muscular relaxation and neuro-inhibition. It consists of a table with an adjustable overhead weight that, in place of the therapist's hands, presses on the back of a prone patient.

O.5850	Powered muscle stimulator	2	A powered muscle stimulator is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.
O.5860	Ultrasound and muscle stimulator	2,3	(a)Ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions -- (1)Identification. An ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies. The device also passes electrical currents through the body area to stimulate or relax muscles.
O.5880	Multi-function physical therapy table	2	A multi-function physical therapy table is a device intended for medical purposes that consists of a motorized table equipped to provide patients with heat, traction, and muscle relaxation therapy.
O.5900	Powered traction equipment	2	Powered traction equipment consists of powered devices intended for medical purposes for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body.
O.5925	Traction accessory	1	A traction accessory is a nonpowered accessory device intended for medical purposes to be used with powered traction equipment to aid in exerting therapeutic pulling forces on the patient's body. This generic type of device includes the pulley, strap, head halter, and pelvic belt.
O.9999	Others(Physical Medicine Devices)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.
P.0002	Blood irradiator to prevent graft versus host disease	2	An ionizing radiation blood irradiator is a device that generates ionizing radiation to irradiate blood and blood products (blood packs), making the lymphoid cells in the blood deactivate for the prevention of graft versus host disease (GVHD).
P.1000	Magnetic resonance diagnostic device	2	A magnetic resonance diagnostic device is intended for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced. The device includes hydrogen-1 (proton) imaging, sodium-23 imaging, hydrogen-1 spectroscopy, phosphorus-31 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information).
P.1100	Scintillation (gamma) camera	1	A scintillation (gamma) camera is a device intended to image the distribution of radionuclides in the body by means of a photon radiation detector. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

P.1110	Positron camera	1	A positron camera is a device intended to image the distribution of positron-emitting radionuclides in the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.
P.1130	Nuclear whole body counter	1	A nuclear whole body counter is a device intended to measure the amount of radionuclides in the entire body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
P.1170	Bone densitometer	2	A bone densitometer is a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
P.1180	Bone Sonometer	2	A bone sonometer is a device that transmits ultrasound energy into the human body to measure acoustic properties of bone that indicate overall bone health and fracture risk. The primary components of the device are a voltage generator, a transmitting transducer, a receiving transducer, and hardware and software for reception and processing of the received ultrasonic signal.
P.1200	Emission computed tomography system	2	An emission computed tomography system is a device intended to detect the location and distribution of gamma ray- and positron-emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.
P.1220	Fluorescent scanner	2	A fluorescent scanner is a device intended to measure the induced fluorescent radiation in the body by exposing the body to certain x-rays or low-energy gamma rays. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts and accessories.
P.1300	Nuclear rectilinear scanner	1	A nuclear rectilinear scanner is a device intended to image the distribution of radionuclides in the body by means of a detector (or detectors) whose position moves in two directions with respect to the patient. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.
P.1310	Nuclear tomography system	2	A nuclear tomography system is a device intended to detect nuclear radiation in the body and produce images of a specific cross-sectional plane of the body by blurring or eliminating detail from other planes. This generic type of devices may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

P.1320	Nuclear uptake probe	1	A nuclear uptake probe is a device intended to measure the amount of radionuclide taken up by a particular organ or body region. This generic type of device may include a single or multiple detector probe, signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
P.1330	Nuclear whole body scanner	1	A nuclear whole body scanner is a device intended to measure and image the distribution of radionuclides in the body by means of a wide-aperture detector whose position moves in one direction with respect to the patient. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.
P.1350	Nuclear scanning bed	1	A nuclear scanning bed is an adjustable bed intended to support a patient during a nuclear medicine procedure.
P.1360	Radionuclide dose calibrator	2	A radionuclide dose calibrator is a radiation detection device intended to assay radionuclides before their administration to patients.
P.1390	Radionuclide rebreathing system	2	A radionuclide rebreathing system is a device intended to be used to contain a gaseous or volatile radionuclide or a radionuclide-labeled aerosol and permit it to be respired by the patient during nuclear medicine ventilatory tests (testing process of exchange between the lungs and the atmosphere). This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
P.1400	Nuclear sealed calibration source	1	A nuclear sealed calibration source is a device that consists of an encapsulated reference radionuclide intended for calibration of medical nuclear radiation detectors.
P.1410	Nuclear electrocardiograph synchronizer	1	A nuclear electrocardiograph synchronizer is a device intended for use in nuclear radiology to relate the time of image formation to the cardiac cycle during the production of dynamic cardiac images.
P.1540	Nonfetal ultrasonic monitor	2	A nonfetal ultrasonic monitor is a device that projects a continuous high-frequency sound wave into body tissue other than a fetus to determine frequency changes (doppler shift) in the reflected wave and is intended for use in the investigation of nonfetal blood flow and other nonfetal body tissues in motion. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
P.1550	Ultrasonic pulsed doppler imaging system	2	An ultrasonic pulsed doppler imaging system is a device that combines the features of continuous wave doppler-effect technology with pulsed-echo effect technology and is intended to determine stationary body tissue characteristics, such as depth or location of tissue interfaces or dynamic tissue characteristics such as velocity of blood or tissue motion. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
P.1560	Ultrasonic pulsed echo imaging system	2	An ultrasonic pulsed echo imaging system is a device intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

P.1570	Diagnostic ultrasonic transducer	2	A diagnostic ultrasonic transducer is a device made of a piezoelectric material that converts electrical signals into acoustic signals and acoustic signals into electrical signals and intended for use in diagnostic ultrasonic medical devices. Accessories of this generic type of device may include transmission media for acoustically coupling the transducer to the body surface, such as acoustic gel, paste, or a flexible fluid container.
P.1600	Angiographic x-ray system	2	An angiographic x-ray system is a device intended for radiologic visualization of the heart, blood vessels, or lymphatic system during or after injection of a contrast medium. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
P.1610	Diagnostic x-ray beam-limiting device	2	A diagnostic x-ray beam-limiting device is a device such as a collimator, a cone, or an aperture intended to restrict the dimensions of a diagnostic x-ray field by limiting the size of the primary x-ray beam.
P.1620	Cine or spot fluorographic x-ray camera	2	A cine or spot fluorographic x-ray camera is a device intended to photograph diagnostic images produced by x-rays with an image intensifier.
P.1630	Electrostatic x-ray imaging system	2	An electrostatic x-ray imaging system is a device intended for medical purposes that uses an electrostatic field across a semiconductive plate, a gas-filled chamber, or other similar device to convert a pattern of x-radiation into an electrostatic image and, subsequently, into a visible image. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
P.1640	Radiographic film marking system	1	A radiographic film marking system is a device intended for medical purposes to add identification and other information onto radiographic film by means of exposure to visible light.
P.1650	Image-intensified fluoroscopic x-ray system	2	An image-intensified fluoroscopic x-ray system is a device intended to visualize anatomical structures by converting a pattern of x-radiation into a visible image through electronic amplification. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
P.1660	Non-image-intensified fluoroscopic x-ray system	2	A non-image-intensified fluoroscopic x-ray system is a device intended to be used to visualize anatomical structures by using a fluorescent screen to convert a pattern of x-radiation into a visible image. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
P.1670	Spot-film device	2	A spot-film device is an electromechanical component of a fluoroscopic x-ray system that is intended to be used for medical purposes to position a radiographic film cassette to obtain radiographs during fluoroscopy.
P.1680	Stationary x-ray system	2	A stationary x-ray system is a permanently installed diagnostic system intended to generate and control x-rays for examination of various anatomical regions. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

P.1700	Diagnostic x-ray high voltage generator	1	A diagnostic x-ray high voltage generator is a device that is intended to supply and control the electrical energy applied to a diagnostic x-ray tube for medical purposes. This generic type of device may include a converter that changes alternating current to direct current, filament transformers for the x-ray tube, high voltage switches, electrical protective devices, or other appropriate elements.
P.1710	Mammographic x-ray system	2	A mammographic x-ray system is a device intended to be used to produce radiographs of the breast. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
P.1715	Full-field digital mammography system	2	A full-field digital mammography system is a device intended to produce planar digital x-ray images of the entire breast. This generic type of device may include digital mammography acquisition software, full-field digital image receptor, acquisition workstation, automatic exposure control, image processing and reconstruction programs, patient and equipment supports, component parts, and accessories. Classification. Class II
P.1720	Mobile x-ray system	2	A mobile x-ray system is a transportable device system intended to be used to generate and control x-ray for diagnostic procedures. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
P.1730	Photofluorographic x-ray system	2	A photofluorographic x-ray system is a device that includes a fluoroscopic x-ray unit and a camera intended to be used to produce, then photograph, a fluoroscopic image of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
P.1740	Tomographic x-ray system	2	A tomographic x-ray system is an x-ray device intended to be used to produce radiologic images of a specific cross-sectional plane of the body by blurring or eliminating detail from other planes. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
P.1750	Computed tomography x-ray system	2	A computed tomography x-ray system is a diagnostic x-ray system intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
P.1760	Diagnostic x-ray tube housing assembly	1	A diagnostic x-ray tube housing assembly is an x-ray generating tube encased in a radiation-shielded housing that is intended for diagnostic purposes. This generic type of device may include high voltage and filament transformers or other appropriate components.
P.1820	Pneumoencephalographic chair	2	A pneumoencephalographic chair is a chair intended to support and position a patient during pneumoencephalography (x-ray imaging of the brain).

P.1830	Radiologic patient cradle	1	A radiologic patient cradle is a support device intended to be used for rotational positioning about the longitudinal axis of a patient during radiologic procedures.
P.1840	Radiographic film	1	Radiographic film is a device that consists of a thin sheet of radiotransparent material coated on one or both sides with a photographic emulsion intended to record images during diagnostic radiologic procedures.
P.1850	Radiographic film cassette	2	A radiographic film cassette is a device intended for use during diagnostic x-ray procedures to hold a radiographic film in close contact with an x-ray intensifying screen and to provide a light-proof enclosure for direct exposure of radiographic film.
P.1860	Radiographic film/cassette changer	2	A radiographic film/cassette changer is a device intended to be used during a radiologic procedure to move a radiographic film or cassette between x-ray exposures and to position it during the exposure.
P.1870	Radiographic film/cassette changer programmer	2	A radiographic film/cassette changer programmer is a device intended to be used to control the operations of a film or cassette changer during serial medical radiography.
P.1900	Automatic radiographic film processor	2	An automatic radiographic film processor is a device intended to be used to develop, fix, wash, and dry automatically and continuously film exposed for medical purposes.
P.1910	Radiographic grid	1	A radiographic grid is a device that consists of alternating radiolucent and radiopaque strips intended to be placed between the patient and the image receptor to reduce the amount of scattered radiation reaching the image receptor.
P.1920	Radiographic head holder	1	A radiographic head holder is a device intended to position the patient's head during a radiographic procedure.
P.1960	Radiographic intensifying screen	1	A radiographic intensifying screen is a device that is a thin radiolucent sheet coated with a luminescent material that transforms incident x-ray photons into visible light and intended for medical purposes to expose radiographic film.
P.1970	Radiographic ECG/respirator synchronizer	1	A radiographic ECG/respirator synchronizer is a device intended to be used tocoordinatean x-ray film exposure with the signal from an electrocardiograph (ECG) or respirator at a predetermined phase of the cardiac or respiratory cycle.
P.1980	Radiographic table	1	A radiologic table is a device intended for medical purposes to support a patient during radiologic procedures. The table may be fixed or tilting and may be electrically powered.
P.1990	Transilluminator for breast evaluation	3	A transilluminator, also known as a diaphanoscope or lightscanner, is an electrically powered device that uses low intensity emissions of visible light and near-infrared radiation (approximately 700-1050 nanometers (nm)), transmitted through the breast, to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases, or abnormalities.
P.2010	Medical image storage device	1	A medical image storage device is a device that provides electronic storage and retrieval functions for medical images. Examples include devices employing magnetic and optical discs, magnetic tape, and digital memory.

P.2020	Medical image communication device	1	A medical image communications device provides electronic transfer of medical image data between medical devices. It may include a physical communications medium, modems, interfaces, and a communications protocol.
P.2030	Medical image digitizer	2	A medical image digitizer is a device intended to convert an analog medical image into a digital format. Examples include Iystems employing video frame grabbers, and scanners which use lasers or charge-coupled devices.
P.2040	Medical image hardcopy device	2	A medical image hardcopy device is a device that produces a visible printed record of a medical image and associated identification information. Examples include multiformat cameras and laser printers.
P.2050	Picture archiving and communication system	2	A picture archiving and communications system is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. Its hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification.
P.5050	Medical charged-particle radiation therapy system	2	A medical charged-particle radiation therapy system is a device that produces by acceleration high energy charged particles (e.g., electrons and protons) intended for use in radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.
P.5300	Medical neutron radiation therapy system	2	A medical neutron radiation therapy system is a device intended to generate high-energy neutrons for radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment support, treatment planning computer programs, component parts, and accessories.
P.5650	Manual radionuclide applicator system	1	A manual radionuclide applicator system is a manually operated device intended to apply a radionuclide source into the body or to the surface of the body for radiation therapy. This generic type of device may include patient and equipment supports, component parts, treatment planning computer programs, and accessories.
P.5700	Remote controlled radionuclide applicator system	2	A remote controlled radionuclide applicator system is an electromechanical or pneumatic device intended to enable an operator to apply, by remote control, a radionuclide source into the body or to the surface of the body for radiation therapy. This generic type of device may include patient and equipment supports, component parts, treatment planning computer programs, and accessories.
P.5710	Radiation therapy beam-shaping block	2	A radiation therapy beam-shaping block is a device made of a highly attenuating material (such as lead) intended for medical purposes to modify the shape of a beam from a radiation therapy source.
P.5720	Rectal balloon for prostate immobilization	2	A rectal balloon for prostate immobilization is a single use, inflatable, non-powered positioning device placed in the rectum to immobilize the prostate in patients undergoing radiation therapy. The device is intended to be used during all the phases of radiation therapy, including treatment planning, image verification, and radiotherapy delivery.

P.5725	Absorbable perirectal spacer	2	An absorbable perirectal spacer is composed of biodegradable material that temporarily positions the anterior rectal wall away from the prostate during radiotherapy for prostate cancer with the intent to reduce the radiation dose delivered to the anterior rectum. The absorbable spacer maintains space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.
P.5730	Radionuclide brachytherapy source	2	A radionuclide brachytherapy source is a device that consists of a radionuclide which may be enclosed in a sealed container made of gold, titanium, stainless steel, or platinum and intended for medical purposes to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy.
P.5740	Radionuclide teletherapy source	1	A radionuclide teletherapy source is a device consisting of a radionuclide enclosed in a sealed container. The device is intended for radiation therapy, with the radiation source located at a distance from the patient's body.
P.5750	Radionuclide radiation therapy system	2	A radionuclide radiation therapy system is a device intended to permit an operator to administer gamma radiation therapy, with the radiation source located at a distance from the patient's body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts (including beam-limiting devices), and accessories.
P.5770	Powered radiation therapy patient support assembly	2	A powered radiation therapy patient support assembly is an electrically powered adjustable couch intended to support a patient during radiation therapy.
P.5780	Light beam patient position indicator	1	A light beam patient position indicator is a device that projects a beam of light (incoherent light or laser) to determine the alignment of the patient with a radiation beam. The beam of light is intended to be used during radiologic procedures to ensure proper positioning of the patient and to monitor alignment of the radiation beam with the patient's anatomy.
P.5840	Radiation therapy stimulation system	2	A radiation therapy simulation system is a fluoroscopic or radiographic x-ray system intended for use in localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field produced. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.
P.5900	X-ray radiation therapy system	2	An x-ray radiation therapy system is a device intended to produce and control x-rays used for radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.
P.5930	Therapeutic x-ray tube housing assembly	2	A therapeutic x-ray tube housing assembly is an x-ray generating tube encased in a radiation-shielded housing intended for use in radiation therapy. This generic type of device may include high-voltage and filament transformers or other appropriate components when contained in radiation-shielded housing.

P.6500	Personnel protective shield	1	A personnel protective shield is a device intended for medical purposes to protect the patient, the operator, or other persons from unnecessary exposure to radiation during radiologic procedures by providing an attenuating barrier to radiation. This generic type of device may include articles of clothing, furniture, and movable or stationary structures.
P.9999	Others(Radiology Devices)	1,2,3	The products excluded from the above-classification are adopted in this classification and specified by the central competent health authority.