Ministry of Food and Drug Safety Notice No. 2023-023

Partial revision of medical device standards (draft)

2023. 1. 18.

Ministry of Food and Drug Safety

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In the case of partial revision of the "Standard Specifications for Medical Devices", it is necessary to inform the public in advance.

Article 46 of the ÿAdministrative Procedure Actÿ

In accordance with this, we announce as follows.

January 18, 2023

Minister of Food and Drug Safety

Administrative notice of partial revision of ÿMedical Device Standards and Specificationsÿ

1. Reasons for revision

Regarding medical device standards, new establishments and revisions are made to conform to international standards.

public health by improving the safety and quality level of domestic distribution medical devices through

I want to block hazards in advance

2. Highlights

go. Establishment of medical device standards (Annex Table 1, Annex 2, Annex 3)

7 types of high-intensity focused ultrasound surgery equipment and X-ray equipment for mammography

Establishment of new standards to secure the safety and performance of a product

1) Medical supplies and dental materials: 2 types

2) Apparatus/Machine: 4 types

3) Class 1 medical device: 1 type

me. Conformity to international standards for medical device standards (Annex Table 1, Annex 2, Annex Table 3)

Test standards and test rooms for 24 types of gas anesthesia devices and stationary incubators

Securing product performance and safety by applying international standards (IEC, ISO)

1) Medical supplies and dental materials: 7 types

2) Apparatus/Machine: 16 types

3) Class 1 medical device: 1 type

3. Submit comments

Organizations that have opinions on the partial amendment notice (draft) of ÿStandards for Medical Devicesÿ or the individual must submit a written opinion by March 23, 2023 stating the following:

Minister of Drug Safety (Reference: Medical Device Standards and Informatization Team, postal code: 28159, Address: Osong Health & Medical Center, 187 Osong Life 2-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do Administration Town Ministry of Food and Drug Safety, phone 043-719-5653, fax 043-719-5650, Please submit by e-mail to sojung@korea.kr).

go. Opinion by item on the matters to be announced (whether for or against and why)

me. Name (in the case of an organization, the name of the organization and the name of its representative), address and phone number

all. Other notes

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ÿMedical Device Standardsÿ in accordance with Article 19 of the ÿMedical Device Actÿ as follows want to amend.

month day 2023

Minister of Food and Drug Safety

ÿMedical Device Standardsÿ Partly Revision Notification (draft)

ÿMedical Device Standardsÿ Annex 1, Annex 2 and Annex 3 are newly established as attached sheets. or amend

Addenda

Article 1 (Effective Date) This Notice shall be enforced from the date on which 6 months have elapsed since the notice.

However, “10. Non-absorbable suture”, “17. Heat-polymerized denture base resin”, “21. Chemically cured denture base resin”, Appendix 2, “63. Dental Extraoral X-ray Chi”, “64. Dental intraoral X-ray device” is effective from the date of notification.

Article 2 (Interim measures)

medical device manufacturing (import) permit application, manufacturing (import) certification application, manufacturing (import)

Report, permission change application form, certification change certification application form, medical devices

Application for approval of clinical trial plan (change) and review request such as technical documents

Follow the previous rules.