NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** United States of America  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:** Food and Drug Administration (FDA), Health and Human Services (HHS) [1491]  **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**  Please submit comments to: USA WTO TBT Enquiry Point, Email: usatbtep@nist.gov |
| **3.** | **Notified under Article 2.9.2 [ ],** **2.10.1 [ ],** **5.6.2 [ ],** **5.7.1 [ ],** **other:** **[X]** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Flow cytometer instruments; Medical equipment (ICS 11.040) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Medical Devices; Exemption From Premarket Notification: Class II Devices; Flow Cytometer Instruments; Request for Comments (4 page(s), in English) |
| **6.** | **Description of content:** The Food and Drug Administration (FDA or Agency) is announcing its intention to exempt certain flow cytometer instruments from premarket notification requirements, subject to conditions and limitations. The Agency has determined based on established factors that these devices, which are currently regulated by FDA under product code OYE, no longer require premarket notification to provide reasonable assurance of safety and effectiveness. All other class II devices classified under FDA's automated differential cell counter regulation would continue to be subject to premarket notification requirements. FDA is publishing this proposed order to obtain comments regarding this proposed exemption, in accordance with the Federal Food, Drug, and Cosmetic Act (FD&amp;C Act). |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Cost saving and productivity enhancement |
| **8.** | **Relevant documents:**   * 84 Federal Register (FR) 8047, 6 March 2019; Title 21 Code of Federal Regulations (CFR) Part 864. Will appear in the Federal Register when adopted. |
| **9.** | **Proposed date of adoption:** To be determined  **Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 6 May 2019 |
| **11.** | **Texts available from: National enquiry point [** **]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  <https://members.wto.org/crnattachments/2019/TBT/USA/19_2039_00_e.pdf> |