WORLD TRADE ORGANIZATION

G/TBT/N/USA/1605

20 April 2020

(20-3090)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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) [1635] **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):** HIV serological diagnostic and supplemental tests and HIV nucleic acid (NAT) diagnostic and supplemental tests; Diagnostic equipment (ICS 11.040.55), Laboratory medicine (ICS 11.100)
5.	**Title, number of pages and language(s) of the notified document:** Microbiology Devices; Reclassification of Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests (9 page(s), in English)
6.	**Description of content:** Proposed amendment; proposed order - The Food and Drug Administration (FDA or the Agency) is proposing to reclassify certain human immunodeficiency virus (HIV) serological diagnostic and supplemental tests and HIV nucleic acid (NAT) diagnostic and supplemental tests, postamendments class III devices with the product code MZF, into class II (special controls), subject to premarket notification. FDA is also proposing new device classification regulations along with special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness for these devices. FDA is proposing this reclassification on its own initiative. If finalized, this order will reclassify these types of devices from class III (premarket approval) to class II (special controls) and reduce the regulatory burdens associated with these devices, as these types of devices will no longer be required to submit a premarket approval application (PMA) but can instead submit a premarket notification (510(k)) and receive clearance before marketing their device.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety

8.	**Relevant documents:** • 85 Federal Register (FR) 10110, 21 February 2020; Title 21 Code of Federal Regulations (CFR) Part 866: https://www.govinfo.gov/content/pkg/FR-2020-02-21/html/2020-03515.htm https://www.govinfo.gov/content/pkg/FR-2020-02-21/pdf/2020-03515.pdf The docket folder on Regulations.gov provides access to primary and supporting documents for this rulemaking as well as the comments received: https://www.regulations.gov/docket?D=FDA-2019-N-5192
9.	**Proposed date of adoption:** To be determined **Proposed date of entry into force:** To be determined
10.	**Final date for comments:** 21 April 2020
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/2020/TBT/USA/20_2758_00_e.pdf