NOTIFICATION

Addendum

The following communication, dated 17 May 2022, is being circulated at the request of the delegation of the United States of America.

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**Title:** Microbiology Devices; Reclassification of Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests

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| **Reason for Addendum:** | |
| [ ] | Comment period changed - date: |
| [ ] | Notified measure adopted - date: |
| [X] | Notified measure published - date: 16 May 2022 |
| [X] | Notified measure enters into force - date: 15 June 2022 |
| [X] | Text of final measure available from[[1]](#footnote-1):  <https://www.govinfo.gov/content/pkg/FR-2022-05-16/html/2022-10461.htm>  <https://www.govinfo.gov/content/pkg/FR-2022-05-16/pdf/2022-10461.pdf>  <https://members.wto.org/crnattachments/2022/TBT/USA/final_measure/22_3449_00_e.pdf> |
| [ ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |
| [ ] | Content or scope of notified measure changed and text available from1:  New deadline for comments (if applicable): |
| [ ] | Interpretive guidance issued and text available from1: |
| [ ] | Other: |

**Description:** TITLE: Microbiology Devices; Reclassification of Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests

AGENCY: Food and Drug Administration, HHS

ACTION: Final amendment; final order

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is issuing a final order 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. Through this final order, FDA is also adding two new device classification regulations and identifying special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness for these device types. This final order will reduce the regulatory burdens associated with these device types, as manufacturers 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.

This order is effective 15 June 2022.

This final amendment; final order and the proposed amendment; proposed order notified as [G/TBT/N/USA/1605](https://eping.wto.org/en/Search?domainIds=1&documentSymbol=usa%2F1605) are identified by Docket Number FDA-2019-N-5192. The Docket Folder is available on Regulations.gov at <https://www.regulations.gov/docket/FDA-2019-N-5192/document> and provides access to primary and supporting documents as well as comments received. Documents are also accessible from [Regulations.gov](http://www.regulations.gov/) by searching the Docket Number.

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1. This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained. [↑](#footnote-ref-1)