DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2025–N–0710]

Medical Devices; Immunology and Microbiology Devices; Classification of the Microbial Nucleic Acid Storage and Stabilization Device

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the microbial nucleic acid storage and stabilization device into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the microbial nucleic acid storage and stabilization device's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective May 9, 2025. The classification was applicable on March 19, 2018.

FOR FURTHER INFORMATION CONTACT: Dina Jerebitski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD 20993–0002, 301–796–2411, *Dina.Jerebitski@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the microbial nucleic acid storage and stabilization device as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or PMA to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On May 25, 2017, FDA received Longhorn Vaccines and Diagnostics LLC's request for De Novo classification of the PrimeStore MTM. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 19, 2018, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 866.2950.[1] We have named the generic type of device ''microbial nucleic acid storage and stabilization device,'' and it is identified as a device that consists of a container and reagents

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of the Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

intended to stabilize microbial nucleic acids in human specimens for subsequent isolation and purification of nucleic acids for further molecular testing. The device is not intended for preserving morphology or viability of microorganisms.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—MICROBIAL NUCLEIC ACID STORAGE AND STABILIZATION DEVICE RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Failure to stabilize pathogen nucleic acid resulting in a false negative result.	General Controls and Special Controls (1) (21 CFR 866.2950(b)(1)), (2) (21 CFR 866.2950(b)(2)), and (3) (21 CFR 866.2950(b)(3)).
Failure to inactivate the specimen	General Controls and Special Controls (1) (21 CFR 866.2950(b)(1)); (2)(i) (21 CFR 866.2950(b)(2)(i)), (2)(ii) (21 CFR 866.2950(b)(2)(ii)), and (2)(iv) (21 CFR 866.2950(b)(2)(iv)); and (3)(i) (21 CFR 866.2950(b)(3)(i)), (3)(ii) (21 CFR 866.2950(b)(3)(ii)), and (3)(iv) (21 CFR 866.2950(b)(3)(iv)).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo Classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICORBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 866.2950 to subpart C to read as follows:

§ 866.2950 Microbial nucleic acid storage and stabilization device.

(a) *Identification.* A microbial nucleic acid storage and stabilization device is a device that consists of a container and reagents intended to stabilize microbial nucleic acids in human specimens for subsequent isolation and purification of nucleic acids for further molecular testing. The device is not intended for preserving morphology or viability of microorganisms.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The intended use for the labeling required under § 809.10 of this chapter must include a detailed description of microorganisms and types of human specimens intended to be preserved.

(2) The labeling required under § 809.10(b) of this chapter must include the following:

(i) A detailed device description, including all device components;

(ii) Performance characteristics from applicable analytical studies, including nucleic acid stability and microorganism inactivation;

(iii) A limiting statement that erroneous results may occur when the transport device is not compatible with molecular testing; and

(iv) A limiting statement that the device has only been validated to preserve the representative microorganisms used in the analytical studies.

(3) Design verification and validation must include the following:

(i) Overall device design, including all device components and all control elements incorporated into the analytical validation procedures;

(ii) Thorough description of the microorganisms and methodology used in the validation of the device including, extraction platforms and assays used for the detection of preserved nucleic acids; and

(iii) The limit of detection (LoD) of the molecular test used to establish microorganism nucleic acid stability.

Dated: May 5, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2025–0218]

RIN 1625–AA08

Special Local Regulation; Ohio River, Cincinnati, OH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local