

(2) If there is any play found during any check required by paragraph (g)(1) of this AD, before further flight, accomplish corrective actions in accordance with a method approved by the Manager, International Validation Branch, FAA; or EASA; or AHD's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(h) No Reporting Requirement

Although the material referenced in EASA AD 2026-0152 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD and email to: AMOC@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Additional Information

For more information about this AD, contact Aryanna Sanchez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (817) 222-4058; email: aryanna.t.sanchez@faa.gov.

(k) Material Incorporated by Reference

None.

Issued on October 6, 2026.

Steven W. Thompson,

Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2026-20722 Filed 10-7-26; 11:15 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2026-N-10994]

Medical Devices; Immunology and Microbiology Devices; Classification of the Hematopoietic Cell Enrichment Kit

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the hematopoietic cell enrichment kit 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 classification of the hematopoietic cell enrichment kit. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the 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 October 9, 2026. The classification was applicable on November 6, 2023.

FOR FURTHER INFORMATION CONTACT:

Allen Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3248, Silver Spring, MD 20993-0002, 301-796-4806, Allen.Williams@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the hematopoietic cell enrichment kit into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. 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 into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (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 (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 classification 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 premarket notification (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 premarket approval application 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 December 12, 2022, FDA received STEMCELL Technologies Canada Inc.’s request for De Novo classification of the EasySep Human Bone Marrow CD138 Positive Selection Kit. 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 the safety and effectiveness of the device, 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 section 513(a)(1)(B) of the FD&C Act). 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 November 6, 2023, 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 866.6120.¹ We have named the generic type of device “hematopoietic cell enrichment kit,” and it is identified as an in vitro diagnostic device intended for the selection and enrichment of specific hematopoietic cells from human whole blood and/or bone marrow collected from patients with hematological malignancies using immunomagnetic bead-based selection. It is intended for use with diagnostic assays as part of the pre-analytical workflow.

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

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR HEMATOPOIETIC CELL ENRICHMENT KITS

Identified risks to health	Mitigation measures
Failure to perform as expected due to errors in enrichment, contributing to false positive or false negative results, or failure to produce results in downstream assays.	Use of certain specimen collection devices. Certain design verification and validation, including certain studies and risk mitigation analysis. Certain labeling information, including limitations, device descriptions, methodology and protocols, and performance information.
Incorrect interpretation of enrichment results by the lab	Certain labeling information, including limitations, device descriptions, methodology and protocols, and performance information. Certain design verification and validation, including certain studies and risk mitigation analysis.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. 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 final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for hematopoietic cell enrichment kits. This device is therefore 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 normally 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 management 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 MICROBIOLOGY DEVICES

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

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

■ 2. Add § 866.6120 to subpart G to read as follows:

§ 866.6120 Hematopoietic cell enrichment kit.

(a) Identification. A hematopoietic cell enrichment kit is an in vitro diagnostic device intended for the selection and enrichment of specific

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 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.

hematopoietic cells from human whole blood and/or bone marrow collected from patients with hematological malignancies using immunomagnetic bead-based selection. It is intended for use with diagnostic assays as part of the pre-analytical workflow.

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

(1) Any sample collection device used must be FDA-cleared, -approved, or -classified as 510(k) exempt (stand-alone or as part of a test system) for the collection of the sample types with which this device is intended to be used; alternatively, the sample collection device must be cleared in a premarket submission as a part of this device.

(2) The intended use statement must include:

(i) The intended use specimen type (*i.e.*, human whole blood and/or bone marrow) for each malignancy for which acceptable enrichment has been demonstrated and documented using the minimum volume required to ensure a 95 percent accurate call rate when the cell concentration is at the limit of detection, per the device labeling.

(ii) A detailed description of the cell enrichment target(s).

(iii) A statement that the end-user is responsible for validation of this device for use with the assay.

(3) The labeling required under § 809.10(b) of this chapter must include:

(i) Detailed specifications and procedures, appropriately supported by replicate and stability data, for sample collection, processing, and storage, including acceptable ranges of deviation.

(ii) A detailed device description, including all device parts (*e.g.*, instruments and associated user manuals, antibody(ies), reagents, and consumables) and their use within the enrichment procedure.

(iii) Prominent and conspicuous limiting statements clearly explaining:

(A) Any end-user validation required for use with specific tests and collection devices.

(B) Bone marrow stability is severely compromised after 48 hours (or, alternatively, a different timeframe supported by appropriate specimen stability data required under paragraph (4)(i)(E) of this section).

(C) The device is intended only for enriching hematopoietic cell specimens for use in further processing or analysis using additional independent methods.

(D) Results from the device do not provide information regarding any health conditions.

(E) The device is not intended for cell enumeration.

(F) A detailed summary of the studies required under paragraph (b)(4) of this section.

(4) Design verification and validation must include:

(i) Detailed documentation of the following studies for each intended specimen type and malignancy combination, including the study protocols containing descriptions of the test methods, prescribed methods of data analysis and acceptance criteria, final study reports, and data line listings:

(A) Recovery study data demonstrating the range of the device.

(B) A study demonstrating the device limit of detection by demonstrating the minimum number of cells within a prespecified volume that the device is capable of enriching and the percent enrichment when the concentration of cells is established, using a flow cytometry reference method determined to be acceptable by FDA.

(C) A study demonstrating device reproducibility, including multiple operators at each site using the specified enrichment method(s) and protocol. The evaluation must include multiple runs, different instruments, and three different reagent lots. The study must include specimens with low, medium, and high starting enrichment target levels and result in enrichment and acceptable precision at each level. The study must include specimens containing different genetic alterations representative of the cancer indication or condition.

(D) A study demonstrating device specificity, including interference, to evaluate the impact on cell enrichment.

(E) Studies performed to support the stability of samples using the indicated specimen collection method(s) under various storage times, as applicable.

(ii) Detailed documentation of studies performed to demonstrate on-board and in-use reagent stability, including studies to demonstrate reagent shelf life.

(iii) A shipping-stability study, separate from the on-board and in-use reagent stability study, that demonstrates acceptable stability of the parts that comprise the device.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-20725 Filed 10-8-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2026-N-10996]

Medical Devices; Immunology and Microbiology Devices; Classification of the System for Detection of Nucleic Acid From Non-Viral Microorganism(s) Causing Sexually Transmitted Infections Using Home-Collected Specimens

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the system for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens 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 classification of the system for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the 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 October 9, 2026. The classification was applicable on November 15, 2023.

FOR FURTHER INFORMATION CONTACT:

Himani Bisht, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3106, Silver Spring, MD 20993-0002, 301-796-6189, Himani.Bisht@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the system for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by