

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

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 November 16, 2020, FDA received LetsGetChecked Inc.’s (formerly PrivaPath Diagnostics Inc.) request for

De Novo classification of the Simple 2 Test. 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 15, 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 866.3385.¹ We have named the generic type of device “system for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens,” and it is identified as an in vitro diagnostic system intended for self-collecting specimens in home settings or similar environments and testing in a clinical laboratory for detection of nucleic acids from non-viral microorganism(s) causing sexually transmitted infections. The device is intended to aid in the diagnosis of sexually transmitted infections. The device is intended for prescription use or over-the-counter use.

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 SYSTEMS FOR DETECTION OF NUCLEIC ACID FROM NON-VIRAL MICROORGANISM(S) CAUSING SEXUALLY TRANSMITTED INFECTIONS USING HOME-COLLECTED SPECIMENS

Identified risks to health	Mitigation measures
Risk of false results	Certain labeling information including limitations, device descriptions, performance information, and explanations of procedures. Use of certain specimen collection devices. Certain design verification and validation including documentation of device descriptions, certain analytical studies and clinical studies, and risk analysis strategies.

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.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR SYSTEMS FOR DETECTION OF NUCLEIC ACID FROM NON-VIRAL MICROORGANISM(S) CAUSING SEXUALLY TRANSMITTED INFECTIONS USING HOME-COLLECTED SPECIMENS—Continued

Identified risks to health	Mitigation measures
Failure to correctly interpret test results	Certain labeling information including limitations, device descriptions, performance information, and explanations of procedures. Use of certain specimen collection devices. Certain design verification and validation including documentation of device descriptions, certain analytical studies and clinical studies, and risk analysis strategies.
Failure to correctly operate the device	Certain labeling information including limitations, device descriptions, performance information, and explanations of procedures. Use of certain specimen collection devices. Certain design verification and validation including documentation of device descriptions, certain analytical studies and clinical studies, and risk analysis strategies.

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.

At the time of classification, systems for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens include systems that are intended for prescription use only. Prescription devices are subject to the prescription labeling requirements for in vitro diagnostic products (see 21 CFR 809.10(a)(4) and (b)(5)(ii)).

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 systems for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens. 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 § 866.3385 to subpart D to read as follows:

§ 866.3385 System for detection of nucleic acid from non-viral microorganism(s) causing sexually transmitted infections using home-collected specimens.

(a) *Identification.* This device is an in vitro diagnostic system intended for self-collecting specimens in home settings or similar environments and testing in a clinical laboratory for detection of nucleic acids from non-viral microorganism(s) causing sexually transmitted infections. The device is intended to aid in the diagnosis of sexually transmitted infections. The device is intended for prescription use or over-the-counter use.

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

(1) The test must use a sample collection device that is FDA-cleared, -approved, or -classified as 510(k) exempt with an indication for over-the-counter in vitro diagnostic use in molecular testing; alternatively, the sample collection device must be cleared in a premarket submission as a part of this device in which performance data demonstrate that lay users can correctly collect specimens without health care provider (HCP) supervision.

(2) The intended use in the labeling required under § 809.10 of this chapter must include a description of the following: the analytes the device detects and identifies, the clinical indications for which the test is to be used, the specimen types tested, the specific intended population(s), the name of the testing facility or facilities, as applicable, and other conditions of use as appropriate.

(3) The intended use of the device must only include indications for testing of specimens that are appropriate for collection by lay users for which

there are performance data that demonstrate lay users can correctly collect specimens without HCP supervision.

(4) Design verification and validation must include:

(i) A detailed test description of test components, including reagents, instruments, ancillary materials, control elements, and a detailed explanation of the methodology, including pre-analytical methods for processing of specimens, microorganism target(s), identification of target detection reagents (e.g., primers), internal controls, and computational path from collected raw data to reported results (e.g., how collected raw signals are converted into a reported signal and result), as applicable to the detection method and device design.

(ii) A description of the process from acquisition of the collection kit to results reporting.

(iii) Detailed descriptions of the test procedure, the interpretation of test results for clinical specimens, and acceptance criteria for any quality control testing.

(iv) Detailed documentation and test performance results from a clinical study that includes prospective self-collected samples for each claimed specimen type. This study must be performed on a study population consistent with the intended use population and compare the device's performance to results obtained using a comparator that FDA has determined is appropriate. Detailed documentation from the clinical study must include the clinical study protocol (including a predefined statistical analysis plan), study report, testing results, and results of statistical analyses.

(v) Risk analysis and documentation demonstrating how risk control measures are implemented to address device system hazards, such as failure modes and effects analysis and/or hazard analysis. This must include information that demonstrates the effectiveness of risk control measures and device robustness, including the entire testing procedure from sampling to result interpretation, based on results from the following studies, as applicable per the intended use of the test device: usability studies, user label comprehension studies, and flex studies.

(vi) Detailed documentation of analytical studies, including the limit of detection, inclusivity, cross-reactivity, microbial interference, interfering substances, competitive inhibition, carryover/cross-contamination, specimen stability, within-lab precision, and reproducibility, as applicable.

(vii) Validation data to support specimen integrity during handling and shipping.

(viii) Detailed documentation of reagent stability studies.

(ix) For devices with associated software or instrumentation, a detailed description of device software, including software applications and hardware-based devices that incorporate software. The detailed description must include documentation of verification, validation, hazard analysis, and risk assessment activities.

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

(i) Clear information written in appropriate language for the intended user that includes: instructions for sample collection and sample packaging for shipping and transport to the testing site; an explanation of test results and results interpretation, including instructions on what actions to take based on the test results; and information for technical assistance with the collection kit.

(ii) A frequently asked questions section that provides technical and educational information (e.g., information about notifying sexual partners, how to prevent future infections, what to do if symptoms persist after treatment, directions to resources for further information on the disease and epidemiology).

(iii) Warning and limitation statements, including the following:

(A) A negative test result does not preclude the possibility of infection with other pathogens;

(B) The test system is not a substitute for visits to a healthcare provider. The information provided by the product should not be used to start, stop, or change any course of treatment unless advised by the healthcare provider;

(C) Anyone with recent sexual contact with a person known to have a sexually transmitted infection should visit a healthcare provider for treatment and evaluation as soon as possible (refer to professional guidelines);

(D) Contact a healthcare provider prior to collecting the sample if the user has a condition that makes it difficult to use the test (e.g., problems with vision, handling the test components, or understanding test instructions or results);

(E) Accurate results are dependent on adequate product storage and adherence to the specimen collection and testing procedures;

(F) Failure to follow test procedures can lead to incorrect results; and

(G) The home collection kit must not be used beyond the expiration date. Use

of expired kits can lead to incorrect results.

(iv) Accessioning criteria for acceptability of samples received by the laboratory (e.g., time from sample collection, transport media leakage, integrity of the sample).

(6) The device's labeling must include a prominent hyperlink to the manufacturer's public website where the manufacturer must make the information identified in this section publicly and prominently available. The information must include, written in language appropriate for the intended user:

(i) A brief summary of the purpose of the test.

(ii) Detailed instructions for proper sample collection and shipping procedures, and interpretation of results.

(iii) Required warnings and limitation statements.

(iv) Contact information for technical assistance with the collection kit (e.g., helpline contact information).

(v) For tests intended for over-the-counter use, information on who should and who should not use this test, and directions for further information for a user who might not be appropriate for testing using this device.

(vi) For tests intended for over-the-counter use, information for users on any follow-up actions (e.g., a link for in-person consultation or telehealth visit with an HCP).

(vii) The performance characteristics established in required studies.

(viii) If appropriate (e.g., recommended by the Centers for Disease Control and Prevention, by current well-accepted clinical guidelines, or by published peer-reviewed research, as determined by FDA), information that the clinical performance is inferior in a specific clinical subpopulation or for a specific claimed specimen type.

(ix) If the device is intended to detect antimicrobial resistance markers, limiting statements, as appropriate, indicating that:

(A) Negative results for claimed resistance markers do not indicate susceptibility of detected microorganisms, as resistance markers not measured by the assay or other potential mechanisms of antibiotic resistance may be present;

(B) Detection of resistance markers cannot be definitively linked to specific microorganisms and the source of a detected resistance marker may be an organism not detected by the assay, including colonizing flora;

(C) Detection of antibiotic resistance markers may not correlate with phenotypic gene expression; and

(D) Therapeutic failure or success cannot be determined based on the assay results, since nucleic acids may persist following appropriate antimicrobial therapy.

(7) The outer box label required under § 809.10(a) of this chapter must include the following:

(i) A description of who may use the home collection kit and age of the intended users.

(ii) A list of the components included.

(iii) A list of the components required, but not provided (e.g., software applications needed to complete the process).

(iv) A statement that this is a home sample collection kit which requires shipping of the sample to a laboratory within the specified timeframe to receive results.

(v) A statement that anyone with recent sexual contact with a person known to have a sexually transmitted infection should visit a healthcare provider for treatment and evaluation as soon as possible (refer to professional guidelines).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-20727 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 870

[Docket No. FDA-2026-N-10993]

Medical Devices; Cardiovascular Devices; Classification of the Infant Pulse Rate and Oxygen Saturation Monitor for Over-the-Counter Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the infant pulse rate and oxygen saturation monitor for over-the-counter use 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 infant pulse rate and oxygen saturation monitor for over-the-counter use. 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 8, 2023.

FOR FURTHER INFORMATION CONTACT:

Kimberly Crowley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2272, Silver Spring, MD 20993-0002, 301-796-6017, Kimberly.Crowley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the infant pulse rate and oxygen saturation monitor for over-the-counter use 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 14, 2022, FDA received Owlet Baby Care, Inc.'s request for De Novo classification of the Dream Sock device. 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