(i) Detailed descriptions of the device studies demonstrating the performance of the device, including results; and

(ii) Limiting statements including the following:

(A) The test result is intended as an aid in the management of the patient, and not to be used to replace clinical judgement.

(B) The test result is not to be used to aid in the diagnosis of preeclampsia or conditions resulting from progression of preeclampsia.

(C) The test result is not to be used to aid in decisions of hospital discharge.

(D) The test result is not to be used to aid in decisions of pregnancy delivery.

(E) The test is not intended to inform the healthcare provider about whether or not changes in immediate treatment, including medication or hospitalization, are needed.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–12900 Filed 6–25–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2026–N–6712]

Medical Devices; Immunology and Microbiology Devices; Classification of the SARS-CoV-2 Serology Test

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the SARS-CoV-2 serology test 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 SARS-CoV-2 serology test. We are taking this action because we have determined that classifying the device into class II 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 June 26, 2026. The classification was applicable on May 5, 2023.

FOR FURTHER INFORMATION CONTACT: Maria Esteve-Gasent, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3213, Silver Spring, MD 20993–0002, 301–837–7365, *Maria.Esteve-Gasent@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the SARS-CoV-2 serology test into class II (special controls), which we have determined will provide a reasonable assurance of 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 September 20, 2021, FDA received Ortho-Clinical Diagnostics, Inc.'s request for De Novo classification of the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack and Calibrator. On September 21, 2021, FDA received Ortho-Clinical Diagnostics, Inc.'s request for De Novo classification of the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack and Calibrator. FDA reviewed both requests in order to classify the devices 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 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 devices 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 devices.

Therefore, on May 5, 2023, FDA issued an order to the requester classifying the devices into class II. In this final order, FDA is codifying the classification of the devices by adding 21 CFR 866.3983.[1] We have named the generic type of device ''SARS-CoV-2 serology test,'' and it is identified as a prescription in vitro diagnostic device for the detection of specific binding antibodies to SARS-CoV-2 in clinical specimens. The detection of SARS-CoV-2 antibodies is intended to aid in identifying individuals with an adaptive immune response to SARS-CoV-2. The test is not intended for the diagnosis of acute SARS-CoV-2 infection, nor screening blood, plasma, cells, or tissue donors.

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 SARS-COV-2 SEROLOGY TESTS

Identified risks to health	Mitigation measures
Risk of false test results	Certain labeling information including limitations, device descriptions, explanations of procedures and performance information identified in special controls (1), (3), and (5). Use of certain specimen collection devices identified in special control (2). Certain design verification and validation including documentation of device descriptions, certain analytical studies and clinical studies, and risk analysis strategies identified in special control (4). Testing of characterized samples and labeling information identified in special control (6).
Failure to correctly interpret the test results	Certain labeling information including limitations, device descriptions, explanations of procedures and performance information identified in special controls (1), (3), and (5). Use of certain specimen collection devices identified in special control (2). Certain design verification and validation including documentation of device descriptions, certain analytical studies and clinical studies, and risk analysis strategies identified in special control (4). Testing of characterized samples and labeling information identified in special control (6).
Failure to correctly operate the device	Certain labeling information including limitations, device descriptions, explanations of procedures and performance information identified in special controls (1), (3), and (5). Use of certain specimen collection devices identified in special control (2).

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 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, SARS-CoV-2 serology tests are for prescription use only. Therefore, these devices are subject to the prescription labeling requirements for in vitro diagnostic (IVD) 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 SARS-CoV-2 serology tests. 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

[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.

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 § 866.3983 to subpart D to read as follows:

§ 866.3983 SARS-CoV-2 serology test.

(a) *Identification.* A SARS-CoV-2 serology test is a prescription in vitro diagnostic device for the detection of specific binding antibodies to SARS-CoV-2 in clinical specimens. The detection of SARS-CoV-2 antibodies is intended to aid in identifying individuals with an adaptive immune response to SARS-CoV-2. The test is not intended for the diagnosis of acute SARS-CoV-2 infection, nor screening blood, plasma, cells, or tissue donors.

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

(1) The intended use in the labeling required under § 809.10 of this chapter must include a description of the following: Analytes the device detects, the specimen types tested, the results provided to the end user, the clinical indications for which the test is to be used, the specific intended population(s), the intended use locations including testing location(s) where the device is to be used (if applicable), and other conditions of use, as appropriate.

(2) If sample collection devices are used, any sample collection device used must be FDA-cleared, -approved, or -classified as 510(k) exempt (standalone or as part of a test system) for the collection of specimen types claimed by this device; alternatively, the sample collection device must be cleared in a premarket submission as a part of this device.

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

(i) A detailed device description, including reagents, instruments, ancillary materials, all control elements, and a detailed explanation of the methodology, including all pre-analytical methods for processing of specimens;

(ii) Detailed descriptions of the performance characteristics of the device for each specimen type claimed in the intended use based on analytical studies, including the following, as applicable: Assay cutoff or limit of detection expressed in international standard units, inclusivity, cross-reactivity, interfering substances, competitive inhibition, carryover and cross contamination, matrix equivalency, hook effect, specimen stability, precision, reproducibility, and clinical studies, including the time period in which the clinical performance was established and the variant(s) prevalent in the United States at the time of performance validation;

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

(iv) When applicable, performance results of the analytical study testing of a standardized reference material that FDA has determined is appropriate;

(v) Limiting statements that indicate:

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

(B) A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected;

(C) There is a risk of erroneous results (*i.e.,* negative results) due to the presence of novel emerging viral variants circulating in the intended use population;

(D) The performance characteristics for that analyte were established when [insert predominant strain, subtype, or variant] was prevalent and that due to the propensity of the virus to mutate, new strains emerge over time which may affect the performance of this device and have serious public health implications;

(E) The test results should be interpreted in conjunction with other clinical and laboratory data available to the healthcare provider (as applicable);

(F) Positive and negative predictive values are highly dependent on prevalence;

(G) Accurate results are dependent on adequate specimen collection, transport, storage, and processing (as applicable). Failure to observe proper procedures in any one of these steps can lead to incorrect results;

(H) The test is not intended for donor screening; and

(I) The test is not intended to diagnose acute SARS-CoV-2 infection. An assay that directly detects the virus should be used to evaluate individuals for acute COVID–19, particularly those who have been in contact with the virus.

(vi) For devices intended for the quantitative detection of SARS-CoV-2 antibodies, labeling must include a prominent statement that includes the following: the test calibrators' traceability to a standardized reference material that FDA has determined is appropriate and the limit of blank, limit of detection, and limit of quantitation, with the defined analytical measuring interval.

(4) Design verification and validation must include:

(i) Detailed documentation of performance from a multisite clinical study with an appropriate number of clinical samples (*i.e.,* be appropriately statistically powered) from individuals with recent or prior SARS CoV–2 infection in which the results are compared to results obtained from a comparator that FDA has determined to be appropriate. This study must be conducted in the appropriate laboratory setting to demonstrate clinical performance. For any SARS-CoV-2 serology test intended for use in near-patient settings, a separate clinical study must be conducted in near-patient settings. Documentation from these studies must include study reports with study description, testing results, and all statistical analyses, including an appropriate justification describing how the sample set is representative of the intended use population. These studies must compare the device performance to results obtained from a comparator that FDA has determined to be appropriate. These clinical studies must include testing of unique prospective samples from subjects that are representative of the intended use populations and may, when determined to be acceptable by FDA, include additional characterized clinical samples; or, as an alternative, when determined to be acceptable by FDA, an equivalent sample set;

(ii) For any SARS-CoV-2 antibody test intended for use in near-patient settings, detailed documentation that demonstrates the effectiveness of risk control measures and device robustness, including flex studies, and performance with weakly-reactive samples when used by the intended operators;

(iii) Risk analysis and documentation demonstrating how risk control measures are implemented to address device system hazards, such as failure modes effects analysis and hazard analysis. This documentation must include a detailed description of a protocol (including all procedures and methods) for the continuous monitoring, identification, and handling of genetic mutations and/or novel respiratory pathogen isolates or strains (*e.g.,* regular review of published literature and periodic in silico analysis of target amino acid sequence(s) to detect possible mismatches) that may affect detection of antibody. All results of this protocol, including any findings, must be documented and must include any additional data analysis that is requested by FDA in response to any performance concerns identified under this section or identified by FDA during routine evaluation. Additionally, if requested by FDA, these evaluations must be submitted to FDA within 48 hours of the request for FDA review, and any results that are reasonably interpreted to support the conclusion that novel respiratory pathogen strains or isolates impact the stated expected performance of the device must be sent to FDA immediately to the email address provided in FDA's request;

(iv) Documentation of the specific amino acid sequence of the SARS-CoV-2 target protein(s) that the device utilizes to detect specific antibodies to SARS-CoV-2;

(v) A detailed device description, including device components, ancillary reagents required but not provided, and a detailed explanation of the methodology, including protein sequence target(s) for each analyte, design of target detection reagents, internal and external controls, and computational path from collected raw data to reported result (*e.g.,* how collected raw signals are converted into a reported signal and result), as applicable to the detection method and device design;

(vi) For devices with associated software or instrumentation, documentation must include 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, and hazard analysis and risk assessment activities, including an assessment of the impact of threats and vulnerabilities on device functionality and end users and patients as part of cybersecurity review;

(vii) For devices intended for the detection of SARS-CoV-2 antibodies for which a standardized reference material (that FDA has determined is appropriate) is available, the performance results of an analytical study testing this standardized reference material. Detailed documentation of that study and its results must be provided, including the study protocol, study report, testing results, and all statistical analyses;

(viii) Detailed documentation of analytical studies conducted as appropriate to the technology, specimen types tested, and intended use of the device, including precision, endogenous interferences, cross reactivity, carryover, matrix equivalency, class specificity, hook effect, and sample and reagent stability. Samples selected for use in analytical studies or used to prepare contrived samples for use in analytical studies must be from subjects with clinically relevant circulating antibodies to SARS-CoV-2 in the United States. Cross-reactivity studies must include samples from SARS-CoV-2 antibody negative subjects with antibodies to viruses, high prevalence disease agents, and normal or pathogenic flora. Endogenous interference studies must include SARS-CoV-2 antibody negative and low positive samples with endogenous interference substances, including antibodies present in autoimmune diseases that are reasonably likely to be encountered in clinical specimens under actual use conditions. In addition, for devices intended for the quantitative detection of SARS-CoV-2 antibodies, the information provided must also include the metrological calibration traceability hierarchy to a standardized reference material that FDA has determined is appropriate. As appropriate to the technology and specimen types tested, the information provided to support quantitative tests must also include studies to support the analytical measuring interval, including a limit of blank study, a limit of detection study, an upper and lower limits of quantitation study, a precision study, and a linearity study using clinical samples, and, using a standardized reference material that FDA has determined is appropriate, an accuracy study;

(ix) Detailed documentation of data and protocols, including acceptance criteria, from a real-time reagent stability study must include testing of samples with adequately challenging analyte concentrations and must include shelf-life stability and shipping stability, and, as applicable, in-use and open-kit stability and freeze-thaw stability. The shelf-life stability assessment must include a minimum of three lots;

(x) Detailed documentation of a multisite reproducibility study with testing conducted at a minimum of three sites;

(xi) Final release criteria to be used for manufactured test lots with appropriate evidence that lots released at the extremes of the specifications will meet the claimed analytical and clinical performance characteristics as well as the stability claims; and

(xii) Lot-to-lot precision studies, as appropriate.

(5) For any SARS-CoV-2 antibody test intended for use in near-patient settings, labeling must also include a brief reference sheet (quick reference instructions) for the intended user(s) that includes, at a minimum, the name and intended use of the test, easy to follow step-by-step instructions of all control and sample testing procedures for the claimed sample types, including graphic illustrations targeted towards lay users (as applicable), the result(s) interpretation guidance, warnings and limitation statements, toxicology information and safety considerations for any hazardous materials, information for troubleshooting (*e.g.,* frequently asked questions), and technical assistance with the device (*e.g.,* helpline contact information).

(6) If one of the actions listed in section 564(b)(1)(A) through (D) of the Federal Food, Drug, and Cosmetic Act occurs with respect to one or more of the analytes claimed in the intended use, or if the Secretary of Health and Human Services determines, under section 319(a) of the Public Health Service Act, that a disease or disorder presents a public health emergency, or that a public health emergency otherwise exists, with respect to one or more of the analytes claimed in the intended use:

(i) Within 30 days from the date that FDA notifies manufacturers that characterized samples are available for test evaluation, the manufacturer must have testing performed on the device with those samples in accordance with a standardized protocol considered and determined by FDA to be acceptable and appropriate; and

(ii) Within 60 days from the date that FDA notifies manufacturers that characterized samples are available for test evaluation and continuing until 3 years from that date, the results of the emergency analytical reactivity testing, including the detailed information for the samples tested as described in the certificate of authentication, must be

included as part of the device's labeling in a tabular format.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–12902 Filed 6–25–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2026–N–6709]

Medical Devices; General and Plastic Surgery Devices; Classification of the Breast Implant Suction Retrieval System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the breast implant suction retrieval system 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 breast implant suction retrieval system. We are taking this action because we have determined that classifying the device into class II 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 June 26, 2026. The classification was applicable on April 20, 2023.

FOR FURTHER INFORMATION CONTACT: Cal Rabang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4633, Silver Spring, MD 20993–0002, 301–796–6412, *Cal.Rabang@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the breast implant suction retrieval system into class II (special controls), which we have determined will provide a reasonable assurance of 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 21, 2022, FDA received Empower Medical Devices' request for De Novo classification of the Bateman Bottle. 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 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 April 20, 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 878.4675.[1] We have named the

[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