ACTION: Correcting amendment.

SUMMARY: On March 30, 2026, the Bureau of the Census (Census Bureau) published a final rule in the **Federal Register** entitled '' Streamlining the Census Bureau's Foreign Trade Regulations'', which became effective on March 30, 2026. Subsequent review of the final rule in the **Federal Register** identified an error necessitating corrective action. Accordingly, this final rule issues a non-substantive correction to the Foreign Trade Regulations.

DATES: This rule is effective June 11, 2026.

FOR FURTHER INFORMATION CONTACT: For additional information concerning this final rule, contact Kiesha Downs, Assistant Division Chief, Data User and Respondent Outreach, Economic Management Division, Census Bureau, 4600 Silver Hill Road, Washington, DC 20233–6010 by email at *gtmd.ftrnotices@census.gov*.

SUPPLEMENTARY INFORMATION: The Census Bureau, as delegated by the Secretary of Commerce, is responsible for collecting, compiling, and publishing import and export trade statistics for the United States under the provisions of Title 13, United States Code (U.S.C.), Chapter 9, Section 301(a). Under 13 U.S.C. 302, the Secretary of Commerce is authorized to promulgate regulations necessary or proper to carry out the purposes of and prevent the circumvention of the requirements of Chapter 9 of Title 13. The Secretary also may promulgate regulations covering the confidentiality, publication, and disclosure of information collected under Chapter 9. Under the aforementioned authorities, the Census Bureau is issuing this final rule to revise the note to § 30.2(a)(1)(iv). Due to an oversight, the note inadvertently references a removed section, § 30.16.

Pursuant to 5 U.S.C. 553(b)(B), the Department finds good cause to waive the prior notice and opportunity for public participation requirements of the Administrative Procedure Act for this final rule. The Department has determined that prior notice and opportunity for public participation is unnecessary because this rule only removes a reference to regulatory language that no longer exists. The Department has also determined that delaying the removal of this reference for the sake of carrying out the notice and comment process would be contrary to the public interest, as the reference being removed no longer serves any meaningful function but does pose a risk of confusion and distraction. The Department therefore finds good cause to waive the public notice and comment period under 553(b)(B) and, for the same reason, to waive the 30-day delay in effectiveness under 553(d).

List of Subjects in 15 CFR Part 30

Economic statistics, Exports, Foreign trade, Reporting and recordkeeping requirements.

Dated: June 4, 2026.

George M. Cook,

Chief of Staff to the Under Secretary for Economic Affairs, performing the functions and duties of the Director of the Census Bureau.

For the reasons set out in the preamble, the Census Bureau is amending 15 CFR part 30 as follows:

PART 30—FOREIGN TRADE REGULATIONS

■ 1. The authority citation for 15 CFR part 30 continues to read as follows:

Authority: 5 U.S.C. 301; 13 U.S.C. 301–307; Reorganization plan No. 5 of 1990 (3 CFR 1949–1953 Comp., p. 1004); Department of Commerce Organization Order No. 35–2A, July 22, 1987, as amended and No. 35–2B, December 20, 1996, as amended; Public Law 107–228, 116 Stat. 1350.

■ 2. Amend § 30.2 by:
■ a. Designating the note to paragraph (a)(1)(iv) as note 1 to paragraph (a)(1)(iv); and
■ b. Revising newly redesignated note 1 to paragraph (a)(1)(iv).

The revision reads as follows:

§ 30.2 General requirements for filing Electronic Export Information (EEI).

(a) * * *
(1) * * *
(iv) * * *

Note 1 to paragraph (a)(1)(iv): For the filing requirement for exports destined for a country in Country Group E:1 or E:2 as set forth in supplement no. 1 to 15 CFR part 740, see 15 CFR 758.1(b)(1).

* * * * *

[FR Doc. 2026–11688 Filed 6–10–26; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2026–N–5828]

Medical Devices; Immunology and Microbiology Devices; Classification of the Spinal Muscular Atrophy Newborn Screening Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Spinal Muscular Atrophy newborn screening test 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 Spinal Muscular Atrophy newborn screening test 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 11, 2026. The classification was applicable on November 9, 2022.

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 Spinal Muscular Atrophy (SMA) newborn screening test 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 July 8, 2020, FDA received PerkinElmer Inc.'s request for De Novo classification of the Eonis SCID–SMA 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 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 9, 2022, 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 866.5980.[1] We have named the generic type of device ''Spinal Muscular Atrophy newborn screening test system,'' and it is identified as a prescription device intended to detect homozygous deletion of exon 7 or other similar mutations in the SMN1 (Survival Motor Neuron 1) gene of DNA obtained from dried blood spot specimens on filter paper using a polymerase chain reaction-based test as an aid in screening newborns for SMA. Presumptive positive results are intended to be followed up by diagnostic confirmatory testing.

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 SPINAL MUSCULAR ATROPHY NEWBORN SCREENING TEST SYSTEMS

Identified risks to health	Mitigation measures
Risk of false negative results	Certain design verification and validation identified in special control (1), including certain device description information and documentation of certain analytical studies and clinical studies. Certain labeling information identified in special control (2), including limitations, device descriptions, explanation of procedures, and performance information.
Risk of false positive results	Certain design verification and validation identified in special control (1), including certain device description information and documentation of certain analytical studies and clinical studies. Certain labeling information identified in special control (2), including limitations, device descriptions, explanation of procedures, and performance information.

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, Spinal Muscular Atrophy newborn screening test systems are for prescription use only. Therefore, these devices are subject to the prescription labeling requirements for in vitro diagnostic

[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.

(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 Spinal Muscular Atrophy newborn screening test systems. 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 § 866.5980 to subpart F to read as follows:

§ 866.5980 Spinal Muscular Atrophy newborn screening test system.

(a) *Identification.* A Spinal Muscular Atrophy (SMA) newborn screening test system is a prescription device intended to detect homozygous deletion of exon 7 or other similar mutations in the SMN1 (Survival Motor Neuron 1) gene of DNA obtained from dried blood spot specimens on filter paper using a polymerase chain reaction-based test as an aid in screening newborns for SMA. Presumptive positive results are intended to be followed up by diagnostic confirmatory testing.

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

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

(i) A detailed device description, including all device parts (*e.g.,* instruments and associated user manuals, device software, reagents, calibrators, controls, and consumables) and their use within the testing procedure.

(ii) A detailed explanation of the technology, method(s) of data processing from signal acquisition to result assignment, and pre-specified cut-offs used to interpret the data and generate results and sample reports.

(iii) A description of appropriate internal and external controls that are recommended or provided. The description must identify those control elements that are incorporated into the testing procedure.

(iv) Detailed specifications for the filter paper to be used as part of the device, which must be appropriately labeled for in vitro diagnostic use. Specifications must include punch size and address any properties of the filter paper that may interfere with obtaining test results.

(v) Detailed documentation of the following analytical and clinical studies, 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) A study demonstrating the clinical performance of the device using well characterized prospectively or retrospectively obtained clinical specimens from the intended use population and include homozygous and heterozygous specimens of sufficient number to be determined to be acceptable to FDA. Confirmed positive specimens must have a diagnosis based on confirmatory diagnostic methods. The confirmed positives must include samples from SMA types 1–4. Additionally, samples with SMN2 (Survival Motor Neuron 2) copy number ranging to 4 must be evaluated to determine the risk of false negative (unaffected) results due to assay cross reactivity with the SMN2 gene. A description of the sample collection strategy and accountability must be included. Specimens used in the study must be from patients other than those used to design the test, and validation testing must be based on a pre-specified clinical decision point (*i.e.,* cutoff to distinguish positive and negative results). Results must be summarized in a tabular format comparing interpretation of results to the reference method. Point estimates together with two-sided 95 percent confidence intervals must be provided for the positive percent agreement (sensitivity) and negative percent agreement (specificity). Data must include the retest rate, false positive rate before retest, final false positive rate, and false negative rate. Positive predictive value and negative predictive value must be provided based on published reference to prevalence in the target population.

(B) A study demonstrating device accuracy in comparison to the results obtained by a reference or comparator method determined to be acceptable by FDA.

(C) A study demonstrating device reproducibility generated using a minimum of three sites, of which at least two must be external sites, with at least two operators at each site using the specified extraction method(s) and protocol. The evaluation must include multiple runs, days, different instruments, and different reagent lots. The study must include heterozygous deleted, homozygous deleted, and unaffected specimens. Identical specimens from the same sample panel must be tested at each site. Results must be summarized in a tabular format and reported as standard deviation and 95 percent confidence intervals for the quantitative result and agreement for qualitative results for between-site, between-operator, between-day/run, and within-run (repeatability) for each specimen.

(D) A lot-to-lot reproducibility study of each filter paper intended to be used with the test. The lot-to-lot study must

include a minimum of three lots of each blood spot card that will be validated with the test and be conducted over five nonconsecutive days. The sample panel must consist of at least one positive and one negative specimen. Multiple punches must be obtained from each card for demonstration of homogeneity of the analyte across the dried blood spot. Comparability of the test performance for each filter paper must be demonstrated. Stability and storage of SMN1 DNA on each blood spot card must be demonstrated. Results of the lot-to-lot study must be summarized by providing the agreement within replicates on the assay final result for positive and negative specimens with pre-specified acceptance criteria and 95 percent confidence intervals for all data. Data must be calculated for within-lot and between-lot reproducibility. Data demonstrating the concordance between results across different filter papers must be provided. Study acceptance criteria must be provided and followed.

(E) A study demonstrating device specificity, including interference, carryover/cross-contamination, and analysis of potential off-target genomic sequences, including evaluation of SMN2 amplification, to evaluate the risk of clinically false negative or false positive results.

(F) Studies performed to support the stability of samples using the indicated specimen collection method(s) under various storage times, temperatures, and freeze-thaw conditions, as applicable.

(G) Studies performed to demonstrate on-board and in-use reagent stability, including the test method(s), data analysis plans, acceptance criteria, final study reports, and data line listings. Such documentation must include studies to demonstrate reagent shelf-life for the assay kit, including study protocols containing descriptions of the test method(s), data analysis plans, and acceptance criteria.

(H) Studies performed to evaluate the risk of false positive and false negative results (*e.g.,* validation of the cycle thresholds or other metric, as applicable, used to define the assay reportable range when assessing a range of DNA input, equivalency of different filter paper, and the limit of blank, when determined appropriate by FDA).

(I) A shipping stability study, separate from the study described in paragraph (b)(1)(v)(G) of this section, must be performed that demonstrates acceptable stability of the parts that comprise the kit.

(vi) A detailed description of the impacts of any software, including software applications and hardware-based devices that incorporate software, on the device's functions.

(vii) Identification of all risk mitigation elements used by the device, including a detailed description of all additional procedures, methods, and practices incorporated into the instructions for use that mitigate risks associated with using the device.

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

(i) An intended use statement that includes:

(A) A detailed description of the target(s) the device detects; and

(B) The clinical indications appropriate for test use.

(ii) Prominent and conspicuous limiting statements clearly explaining:

(A) This test is not intended to screen for SMA subtypes other than those specifically stated in the intended use, nor is it intended for carrier screening, as a stand-alone diagnostic test, or for determining eligibility for therapeutic products.

(B) Test results are intended to be used in conjunction with other clinical and diagnostic findings, consistent with professional standards of practice, including confirmation of presumptive positive results by diagnostic confirmatory testing and clinical evaluation, as appropriate.

(iii) Description of the device information required under paragraphs (b)(1)(i) through (iv) of this section.

(iv) A summary of the results of the studies required under paragraphs (b)(1)(v)(A) through (G) of this section.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–11740 Filed 6–10–26; 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–6238]

Medical Devices; Immunology and Microbiology Devices; Classification of the Simple Point-of-Care Device to Directly Detect SARS–CoV–2 Viral Targets From Clinical Specimens in Near-Patient Settings

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the simple point-of-care device to directly detect SARS–CoV–2 viral targets from clinical specimens in near-patient settings 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 simple point-of-care device to directly detect SARS–CoV–2 viral targets from clinical specimens in near-patient settings. 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 11, 2026. The classification was applicable on March 8, 2023.

FOR FURTHER INFORMATION CONTACT: Uwe Scherf, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3110, Silver Spring, MD 20993–0002, 301–796–5456, *Uwe.Scherf@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the simple point-of-care device to directly detect SARS–CoV–2 viral targets from clinical specimens in near-patient settings 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