§ 381.10 [Amended]

■ 14. In § 381.10, paragraph (d)(3) is amended by removing the phrase ''designated State or organized territory listed in § 381.221 that is also identified in § 381.224'' and adding in its place ''State or organized territory designated under both sections 5(c) and 11 of the Act.''

§ 381.145 [Amended]

■ 15. In § 381.145, paragraph (a) is amended by removing the phrase ''in § 331.2 of this chapter'' and adding in its place ''under section 301(c) of the Act.''

§ 381.221 [Removed and reserved]

■ 16. Section 381.221 is removed and reserved.

§ 381.222 [Amended]

■ 17. Amend § 381.222 by:

■ a. In the introductory text removing the phrase ''in § 381.221.''

■ b. In paragraph (e) removing the phrase ''as shown in § 381.224.''

§ 381.224 [Removed and reserved]

■ 18. Section 381.224 is removed and reserved.

§ 381.225 [Amended]

■ 19. In § 381.225, paragraph (a) introductory text is amended by removing the phrase ''listed in § 381.221'' and adding in its place ''designated under section 5(c) of the Act.''

PART 560—STATE-FEDERAL, FEDERAL-STATE COOPERATIVE AGREEMENTS; STATE DESIGNATIONS

■ 20. The authority for part 560 continues to read as follows:

Authority: 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

§ 560.4 [Amended]

■ 21. Amend § 560.4 by:

■ a. In the introductory text

■ i. Removing the phrase ''requirements in part 331 of this chapter'' and adding in its place ''following requirements.''

■ ii. Removing '', including.''

■ b. In paragraph (c) removing the phrase ''in 9 CFR 331.6.''

Done at Washington, DC.

Denise Eblen,

Acting Deputy Under Secretary for the Office of Food Safety.

[FR Doc. 2025–11816 Filed 6–25–25; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2025–N–1245]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Muscular Dystrophy Newborn Screening Test

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the muscular dystrophy newborn screening 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 the muscular dystrophy newborn screening test's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective June 26, 2025. The classification was applicable on December 12, 2019.

FOR FURTHER INFORMATION CONTACT: Irene Tebbs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3526, Silver Spring, MD 20993–0002, 240–402–0283, *Irene.Tebbs@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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

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

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

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

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

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

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

We believe this De Novo classification will enhance patients' access to

beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or 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 4, 2019, FDA received PerkinElmer Inc.'s request for De Novo classification of the GSP Neonatal Creatine Kinase—MM 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, 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 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 December 12, 2019, 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 862.1506.[1] We have named the generic type of device muscular dystrophy newborn screening test, and it is identified as an in vitro diagnostic device that is intended to measure creatine kinase levels obtained from dried blood spot specimens on filter paper from newborns as an aid in screening newborns for muscular dystrophy.

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

TABLE 1—MUSCULAR DYSTROPHY NEWBORN SCREENING TEST RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Risk of False Negative Results	Certain design verification and validation activities, and Certain labeling information.
Risk of False Positive Results	Certain design verification and validation activities, and Certain labeling 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. 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. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

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

IV. Paperwork Reduction Act of 1995

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

List of Subjects in 21 CFR Part 862

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 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

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

■ 2. Add § 862.1506 to subpart B to read as follows:

§ 862.1506 Muscular dystrophy newborn screening test.

(a) *Identification.* A muscular dystrophy newborn screening test is an in vitro diagnostic device intended to measure creatine kinase levels obtained from dried blood spot specimens on filter paper from newborns as an aid in screening newborns for muscular dystrophy.

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

(1) Design verification and validation must include a clinical validation study that includes the following:

(i) Results that demonstrate that the analyte being measured identifies a

[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.

population of newborns who should be subject to follow up diagnostic testing for the condition being screened.

(ii) Predictive value of the device demonstrated using either well characterized prospectively or retrospectively obtained clinical specimens from the intended use population.

(iii) Testing performed by device users who are representative of the types of operators intended to use the test.

(iv) A design that assesses the effects of sample collection and processing steps on test performance.

(v) Tested confirmed positive specimens must have associated diagnostic outcome information based on confirmatory diagnostic methods, or clinically meaningful information regarding the status of the subject must be obtained.

(vi) Data, provided or referenced, generated in samples from the intended use population, that demonstrates the upper reference interval(s), including sufficient samples to calculate the 97.5th and 99.5th percentile information, for the analyte or analytes measured by the device.

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

(i) A warning which states that test results are not intended to diagnose muscular dystrophies.

(ii) A warning which states that test results are intended to be used in conjunction with other clinical and diagnostic findings, consistent with professional standards of practice, including confirmation by alternative methods, and clinical evaluation as appropriate.

(iii) Detailed information on device performance, including the false positive screen rate and the false negative screen rate observed in the clinical study, and any limitations to the data generated in the clinical study (*e.g.,* necessity for testing at a specific age).

(iv) Information on device performance in relevant subgroups (*e.g.,* age of newborn at time of sample collection, birth weight, sex, gestational age) observed in the clinical study.

Dated: June 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11796 Filed 6–25–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2025–N–1447]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Lysosomal Storage Disorder Newborn Screening Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the lysosomal storage disorder 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 the lysosomal storage disorder newborn screening test system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective June 26, 2025. The classification was applicable on February 3, 2017.

FOR FURTHER INFORMATION CONTACT: Ryan Lubert, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD 20993–0002, 240–402–6357, *Ryan.Lubert@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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

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

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

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

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