



December 12, 2019

PerkinElmer Inc.
Brian Ciccariello
Sr. Manager Regulatory Affairs
940 Winter Street
Waltham, Massachusetts 02451

Re: DEN180056

Trade/Device Name: GSP Neonatal Creatine Kinase - MM kit
Regulation Number: 21 CFR 862.1506
Regulation Name: Muscular dystrophy newborn screening test
Regulatory Class: Class II
Product Code: QJE
Dated: October 30, 2019
Received: November 4, 2019

Dear Brian Ciccariello:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the GSP Neonatal Creatine Kinase - MM kit, a prescription device with the following indications for use:

The GSP Neonatal Creatine Kinase-MM kit, is intended for the quantitative in vitro determination of creatine kinase MM-isoform (CK-MM) concentration in blood specimens dried on filter paper as an aid in screening newborns for Duchenne Muscular Dystrophy (DMD) using the GSP instrument.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the GSP Neonatal Creatine Kinase - MM kit, and substantially equivalent devices of this generic type, into Class II under the generic name Muscular dystrophy newborn screening test.

FDA identifies this generic type of device as:

Muscular dystrophy newborn screening test. A muscular dystrophy newborn screening test 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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two

options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On October 11, 2018, FDA received your De Novo requesting classification of the GSP Neonatal Creatine Kinase - MM kit. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the GSP Neonatal Creatine Kinase - MM kit into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the GSP Neonatal Creatine Kinase - MM kit can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Identified Mitigations
Risk of False Negative Results	Certain design verification and validation activities Certain labeling information
Risk of False Positive Results	Certain design verification and validation activities Certain labeling information

In combination with the general controls of the FD&C Act, the Muscular dystrophy newborn screening test is subject to the following special controls:

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 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 21 CFR 809.10(b) 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.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Muscular dystrophy newborn screening test they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Irene Tebbs at 240-402-0283.

Sincerely,

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health