of TREC levels and include samples within the measuring range, samples above and below the measuring range, and samples very near above and below the cutoff value. 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 TREC DNA on each blood spot card must be demonstrated. Results of the lot-to-lot study must be summarized providing the mean, standard deviation, and percentage coefficient of variation in a tabular format. Data must be calculated for within-run, between-run, within-lot, and between-lot. Data demonstrating the concordance between results across different filter papers must be provided. Study acceptance criteria must be provided and followed; and

(I) If applicable, a thermocycler reproducibility study must be performed using thermocyclers from three independent thermocyler manufacturers. The sample panel must consist of specimens with a range of TREC levels and must include samples within the measuring range, samples above and below the measuring range, and samples very near above and below the cutoff value. The study must be done using three filter paper lots and conducted over five nonconsecutive days. Results of the thermocycler reproducibility study must be summarized providing the mean, standard deviation, and percentage coefficient of variance in a tabular format. Data must be calculated for the within-run, between-run, within-lot, between-lot, and between thermocycler manufacturer study results. Study acceptance criteria must be provided and followed.

(iv) Identification of risk mitigation elements used by your device, including a description of all additional procedures, methods, and practices incorporated into the directions for use that mitigate risks associated with testing.

(2) Your § 809.10 compliant labeling must include:

(i) A warning statement that reads ''This test is not intended for diagnostic use, preimplantation or prenatal testing, or for screening of SCID-like syndromes, such as DiGeorge syndrome or Omenn syndrome. It is also not intended to screen for less acute SCID syndromes, such as leaky SCID or variant SCID.'';

(ii) A warning statement that reads ''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) A description of the performance studies listed in paragraph (b)(1)(iii) and a summary of the results; and

(iv) A description of the filter paper specifications required for the test.

Dated: October 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–23496 Filed 10–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2017–N–1609]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Oral Removable Palatal Space Occupying Device for Weight Management and/or Weight Loss

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final order entitled ''Medical Devices; Gastroenterology-Urology Devices; Classification of the Oral Removable Palatal Space Occupying Device for Weight Management and/or Weight Loss'' that appeared in the **Federal Register** of July 28, 2017. The final order was published with an incorrect statement in the preamble about whether FDA planned to exempt the device from premarket notification requirements. This document corrects that error.

DATES: Effective October 30, 2017

FOR FURTHER INFORMATION CONTACT: Mark Antonino, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G208, Silver Spring, MD 20993–0002, 240–402–9980, *mark.antonino@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 28, 2017 (82 FR 35067), FDA published the final order ''Medical Devices; Gastroenterology-Urology Devices; Classification of the Oral Removable Palatal Space Occupying Device for Weight Management and/or Weight Loss.'' The final order published with an incorrect statement in the preamble about whether FDA planned to exempt the device from premarket notification requirements under section 510(k) of the FD&C Act.

In the **Federal Register** of July 28, 2017, (82 FR 35067), the following correction is made: On page 35069, in the first column, the first paragraph is corrected as follows:

''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), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the oral removable palatal space occupying device for weight management and/or weight loss they intend to market.''

Dated: October 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–23490 Filed 10–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2017–N–5934]

Medical Devices; Neurological Devices; Classification of the Non-Electroencephalogram Physiological Signal Based Seizure Monitoring System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the non-electroencephalogram (non-EEG) physiological signal based seizure monitoring 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 non-EEG physiological signal based seizure monitoring 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 October 30, 2017. The classification was applicable on February 16, 2017.

FOR FURTHER INFORMATION CONTACT: Xiaorui Tang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2609, Silver Spring, MD 20993–0002, 301–796–6500, *xiaorui.tang@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the non-EEG physiological signal based seizure monitoring 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 (the 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 by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

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. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). 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 shall 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 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), 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 10, 2014, Brain Sentinel, Inc., submitted a request for De Novo classification of the Brain Sentinel Monitoring and Alerting System. 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 21 U.S.C. 360c(a)(1)(B)). 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 general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 16, 2017, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 882.1580. We have named the generic type of device non-EEG physiological signal based seizure monitoring system, and it is identified as a noninvasive prescription device that collects physiological signals other than EEG to identify physiological signals that may be associated with a seizure.

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—NON-EEG PHYSIOLOGICAL SIGNAL BASED SEIZURE MONITORING SYSTEM RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.
Equipment malfunction leading to injury to users (shock, burn)	Electrical safety, thermal, and mechanical testing; Electromagnetic compatibility testing; and Labeling.
Interference with or from other electrical devices	Electromagnetic compatibility testing.

TABLE 1—NON-EEG PHYSIOLOGICAL SIGNAL BASED SEIZURE MONITORING SYSTEM RISKS AND MITIGATION MEASURES—Continued

Identified risks	Mitigation measures
Incorrect alerts, including: • Missing a seizure—device fails to identify physiological signal that is associated with a seizure; or. • False alarm—device mistakenly identifies a physiological signal as being associated with a seizure.	Clinical performance testing; Non-clinical performance testing; Software verification, validation, and hazard analysis; Labeling; and Training.

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. In order 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 order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, non-EEG physiological signal based seizure monitoring systems are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

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. 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. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 882

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 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

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

■ 2. Add § 882.1580 to subpart B to read as follows:

§ 882.1580 Non-electroencephalogram (EEG) physiological signal based seizure monitoring system.

(a) *Identification.* A non-electroencephalogram (non-EEG) physiological signal based seizure monitoring system is a noninvasive prescription device that collects physiological signals other than EEG to identify physiological signals that may be associated with a seizure.

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

(1) The technical parameters of the device, hardware and software, must be fully characterized and include the following information:

(i) Hardware specifications must be provided. Appropriate verification, validation, and hazard analysis must be performed.

(ii) Software, including any proprietary algorithm(s) used by the device to achieve its intended use, must be described in detail in the Software Requirements Specification (SRS) and Software Design Specification (SDS). Appropriate software verification, validation, and hazard analysis must be performed.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) The device must be designed and tested for electrical, thermal, and mechanical safety and electromagnetic compatibility (EMC).

(4) Clinical performance testing must demonstrate the ability of the device to function as an assessment aid for monitoring for seizure-related activity in the intended population and for the intended use setting. Performance measurements must include positive percent agreement and false alarm rate.

(5) Training must be provided for intended users that includes information regarding the proper use of the device and factors that may affect the collection of the physiologic data.

(6) The labeling must include health care professional labeling and patient-caregiver labeling. The health care professional and the patient-caregiver labeling must include the following information:

(i) A detailed summary of the clinical performance testing, including any adverse events and complications.

(ii) Any instructions technicians and clinicians should convey to patients and caregivers regarding the proper use of the device and factors that may affect the collection of the physiologic data.

(iii) Instructions to technicians and clinicians regarding how to set the device threshold to achieve the intended performance of the device.

Dated: October 24, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–23516 Filed 10–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG 2017–0162]

RIN 1625–AA09

Drawbridge Operation Regulation; Nanticoke River, Seaford, DE

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is modifying the operating schedule that governs the SR 13 Bridge across the Nanticoke River, mile 39.6, in Seaford, Delaware (DE). This modification will require the