(J) Specimen matrix comparison data, if more than one specimen type or anticoagulant can be tested with the device. Samples used for comparison must be from well-characterized patient samples covering the device measuring range.

(K) Clinical performance must be established by comparing data generated by testing samples from the indicated population and the differential diagnosis or non-target disease groups with the device to the clinical diagnostic standard.

(*1*) The diagnosis of NMO and NMOSD must be based on clinical findings, laboratory tests (*e.g.,* serological tests), and radiological tests (*e.g.,* magnetic resonance imaging).

(*2*) The differential diagnosis or non-target disease group must include the applicable diseases or conditions, including but not be limited to the following: Multiple sclerosis, stroke, Lyme disease, shingles, syphilis, human immunodeficiency virus, hepatitis B, tuberculosis, Srgen's syndrome, systemic lupus erythematous, systemic vasculitis, sarcoidosis, Graves' disease, Hashimoto's disease, Type I diabetes, rheumatoid arthritis, Addison's disease, and myasthenia gravis.

(*3*) Diagnosis of diseases or conditions for the differential or non-target disease groups must be based on established diagnostic criteria and clinical evaluation.

(*4*) For all samples, the diagnostic clinical criteria and the demographic information must be collected and provided.

(*5*) The clinical validation results must demonstrate clinical sensitivity and clinical specificity for the test values based on the presence or absence of NMO and NMOSD.

(*6*) The data must be summarized in tabular format comparing the interpretation of results to the disease status.

(L) Expected/reference values generated by testing an adequate number of samples from apparently healthy normal individuals.

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

(2) The device's 21 CFR 809.10(b) compliant labeling must include warnings relevant to the device including:

(i) A warning statement that reads ''The device is for use by laboratory professionals in a clinical laboratory setting''; and

(ii) A warning statement that reads ''The device is not to be used as a stand-alone device but as an adjunct to other clinical information. A diagnosis of Neuromyelitis Optica (NMO) and Neuromyelitis Optica Spectrum Disorders (NMOSD) should not be made on a single test result. The clinical symptoms, results from physical examination, laboratory tests (*e.g.,* serological tests), and radiological tests (*e.g.* Magnetic Resonance Imaging), when appropriate, should always be taken into account when considering the diagnosis of NMO and NMOSD.''

(3) The device's 21 CFR 809.10(b) compliant labeling must include a detailed description of the protocol and performance studies performed in accordance with paragraph (b)(1)(ii) of this section and a summary of the results.

Dated: October 24, 2017.

Anna K. Abram,

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

[FR Doc. 2017–23489 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 866

[Docket No. FDA–2017–N–5924]

Medical Devices; Immunology and Microbiology Devices; Classification of the Newborn Screening Test for Severe Combined Immunodeficiency Disorder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the newborn screening test for severe combined immunodeficiency disorder (SCID) 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 newborn screening test for SCID'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 December 15, 2014.

FOR FURTHER INFORMATION CONTACT: Caryl Giuliano, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5664, Silver Spring, MD 20993–0002, 301–796–2478, *caryl.giuliano@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the newborn screening test for SCID 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 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 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 (PMA) 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 October 14, 2014, Wallac Oy, a subsidiary of PerkinElmer, Inc., submitted a request for De Novo classification of the EnLite Neonatal TREC 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 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 December 15, 2014, 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 866.5930. We have named the generic type of device newborn screening test for SCID, and it is identified as a prescription device intended to measure T-cell receptor excision circle (TREC) DNA obtained from dried blood spot specimens on filter paper using a polymerase chain reaction based test as an aid in screening newborns for SCID. Presumptive positive results must be followed up by diagnostic confirmatory testing. This test is not intended for use as a diagnostic test, 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.

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—NEWBORN SCREENING TEST FOR SCID RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures/21 CFR section
False negative results due to device or user error	Special controls (1) and (2) (21 CFR 866.5930(b)(1) and 21 CFR 866.5930(b)(2)).
False positive results due to device or user error	Special controls (1) and (2) (21 CFR 866.5930(b)(1) and 21 CFR 866.5930(b)(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. 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.

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 the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 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; 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, 360*l,* 371.

■ 2. Add § 866.5930 to subpart F to read as follows:

§ 866.5930 Newborn screening test for severe combined immunodeficiency disorder (SCID).

(a) *Identification.* A newborn screening test for SCID is a prescription device intended to measure T-cell receptor excision circle (TREC) DNA obtained from dried blood spot specimens on filter paper using a polymerase chain reaction based test as an aid in screening newborns for SCID. Presumptive positive results must be followed up by diagnostic confirmatory testing. This test is not intended for use as a diagnostic test, 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.

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

(1) Premarket notification submissions must include the following information:

(i) The intended use must indicate:

(A) The test is not intended for diagnostic use, or for screening of SCID-like syndromes, such as DiGeorge syndrome or Omenn syndrome; and

(B) The test is not intended to screen for less acute SCID syndromes, such as leaky SCID or variant SCID.

(ii) A detailed description of all components in the test that includes:

(A) A detailed description of the test components, all required reagents, instrumentation and equipment, including illustrations or photographs of nonstandard equipment or methods;

(B) Detailed documentation of the device software including, but not limited to, standalone software applications and hardware-based devices that incorporate software;

(C) Specifications for the filter paper, which must be appropriately labeled for in vitro diagnostic use, to be used in specimen collection and how it will be used in specimen collection validation. These specifications must include: descriptive characteristics of the filter paper, instructions on how a lab should choose the appropriate filter paper, chemical properties of the filter paper, interference concerns associated with the chemicals in the filter paper, absorption properties of the filter paper, punch size, absorption capacity, testing for homogeneity of punches, diameter of the circle for the dried blood spot aliquot, absorption time, physical composition, and number and size of punches to be tested;

(D) Methodology and protocols for detection of T-cell receptor excision circles and methods for determination of results. The cutoff must be selected before conducting clinical and analytical studies;

(E) A description of the result outputs along with sample reports. Sample reports must include the scale used in reporting of results (*e.g.,* TREC copies/μL) and the range of values that will be reported out; and

(F) 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.

(iii) Information that demonstrates the performance characteristics of the test, including:

(A) Data that demonstrates the clinical validity of the device, using well characterized prospectively or retrospectively obtained clinical specimens representative of the intended use population. A minimum of 10 to 15 confirmed positive specimens must be obtained from more than 1 site, including relevant annotation, and, at 1 year or beyond, a SCID diagnosis by flow cytometry or clinically meaningful information regarding the status of the subject must be obtained. Additional specimens should have been obtained that are characterized by other disorders that can be found by screening specimens that have low or absent TREC (*e.g.,* other T-cell lymphopenic disorders) to supplement the range of results. The clinical validation study must have a pre-specified clinical decision point (*i.e.,* cutoff to distinguish positive and negative results). Results must be summarized in 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, negative percent agreement, and overall percent agreement. Data must include the retest rate, the false positive rate before retest, the final false positive rate, and the false negative rate;

(B) Device reproducibility data generated, using a minimum of three sites of which at least two must be external sites, with two operators at each site. Each site must conduct a minimum of five runs per operator over five nonconsecutive days evaluating a minimum of six different relevant TREC concentrations that span and are well distributed over the measuring range and include the clinical cutoff. Specimens must include cord blood and cord blood diluted with ABO matched adult blood specimens. Identical specimens from the same sample panel must be tested at each site. Each specimen must be run in triplicate and include controls run in triplicate. Results must be reported as the standard deviation and percentage coefficient of variation for each level tested. Results must also be displayed as a dichotomous variable around the cutoff. Total variation must be partitioned into the sum of within-lab and between-lab variations with pre-specified acceptance criteria and 95 percent confidence intervals for all data. Pre-specified acceptance criteria must be provided and followed;

(C) Device precision data using clinical samples to evaluate the within-lot, between-lot, within-run, between run, and total variation. A range of TREC levels of the specimen must include samples within the measuring range, samples above and below the measuring range, as well as with samples very near above and below the cutoff value. At least three replicates of each specimen must be tested with controls and calibrator(s) according to the device instructions for use. The precision study must use well characterized samples using different lots, instruments, and operators. Results must be summarized in tabular format. Pre-specified acceptance criteria must be provided and followed;

(D) Linearity of the test must be demonstrated using a dilution panel from clinical samples. The range of dilution samples must include samples within the measuring range, samples above and below the measuring range, as well as with samples very near above and below the cutoff value. Results of the regression analysis must be summarized in tabular format and fitted into a linear regression model with the individual measurement results against the dilution factors. Pre-specified acceptance criteria must be provided and followed;

(E) Device analytic sensitivity data, including limit of blank, limit of detection, and limit of quantification;

(F) Device specificity data, including interference, carryover, cross-contamination, and in silico analysis of potential off-target genomic sequences;

(G) Device stability data, including real-time stability of samples under various storage times, temperatures, and freeze-thaw conditions. A separate shipping stability study must be performed;

(H) Lot-to-lot reproducibility study of each filter paper that will be validated 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 specimens with a range

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