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