of persons in the required management positions;

(3) The proposed training authorizations and training specifications requested by the applicant;

(4) The proposed evaluation authorization;

(5) A description of the flight training equipment that the applicant proposes to use;

(6) A description of the applicant's training facilities, equipment, qualifications of personnel to be used, and proposed evaluation plans;

(7) A training program curriculum, including syllabi, outlines, courseware, procedures, and documentation to support the items required in subpart B of this part, upon request by the Administrator;

(8) A description of a recordkeeping system that will identify and document the details of training, qualification, and certification of students, instructors, and evaluators;

(9) A description of quality control measures proposed; and

(10) A method of demonstrating the applicant's qualification and ability to provide training for a certificate or rating in fewer than the minimum hours prescribed in part 61 of this chapter if the applicant proposes to do so.

(c) The facilities and equipment described in paragraph (b)(6) of this section shall—

(1) Be available for inspection and evaluation prior to approval; and

(2) Be in place and operational at the location of the proposed training center prior to issuance of a certificate under this part.

(d) An applicant who meets the requirements of this part and is approved by the Administrator is entitled to—

(1) A training center certificate containing all business names included on the application under which the certificate holder may conduct operations and the address of each business office used by the certificate holder; and

(2) Training specifications, issued by the Administrator to the certificate holder, containing—

(i) The type of training authorized, including approved courses;

(ii) The category, class, and type of aircraft that may be used for training, testing, and checking;

(iii) For each flight simulator or flight training device, the make model, and series of aircraft or the set of aircraft being simulated and the qualification level assigned;

(iv) For each flight simulator and flight training device subject to qualification evaluation by the Administrator, the identification number assigned by the FAA;

(v) The name and address of all satellite training centers, and the approved courses offered at each satellite training center;

(vi) Authorized deviations or waivers from this part; and

(vii) Any other items the Administrator may require or allow.

(e) The Administrator may deny, suspend, revoke, or terminate a certificate under this part if the Administrator finds that the applicant or the certificate holder—

(1) Held a training center certificate that was revoked, suspended, or terminated within the previous 5 years; or

(2) Employs or proposes to employ a person who—

(i) Was previously employed in a management or supervisory position by the holder of a training center certificate that was revoked, suspended, or terminated within the previous 5 years;

(ii) Exercised control over any certificate holder whose certificate has been revoked, suspended, or terminated within the last 5 years; and

(iii) Contributed materially to the revocation, suspension, or termination of that certificate and who will be employed in a management or supervisory position, or who will be in control of or have a substantial ownership interest in the training center.

(3) [RESERVED];

(4) Should not be granted a certificate if the grant would not foster aviation safety.

(f) At any time, the Administrator may amend a training center certificate—

(1) On the Administrator's own initiative, under section 609 of the Federal Aviation Act of 1958 (49 U.S.C. 1429), as amended, and part 13 of this chapter; or

(2) Upon timely application by the certificate holder.

(g) The certificate holder must file an application to amend a training center certificate at least 60 calendar days prior to the applicant's proposed effective amendment date unless a different filing period is approved by the Administrator.

PART 413—LICENSE APPLICATION PROCEDURES

■ 5. The authority citation for part 413 continues to read as follows:

Authority: 51 U.S.C. 50901–50923.

■ 6. Add § 413.17 to read as follows:

§ 413.17 Continuing accuracy of application; supplemental information; amendment.

(a) An applicant must ensure the continuing accuracy and completeness of information furnished to the FAA as part of a pending license or permit application. If at any time the information an applicant provides is no longer accurate and complete in all material respects, the applicant must submit new or corrected information. As part of this submission, the applicant must recertify the accuracy and completeness of the application under § 413.7. If an applicant does not comply with any of the requirements set forth in this paragraph, the FAA can deny the license or permit application.

(b) An applicant may amend or supplement a license or permit application at any time before the FAA issues or transfers the license or permit.

(c) [RESERVED].

Issued under authority provided by 49 U.S.C. 106(f), 40113, 44701–44709, 46111, 46103, and 46301 in Washington, DC.

Brandon Roberts,

Executive Director, Office of Rulemaking.

[FR Doc. 2025–23414 Filed 12–18–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2025–N–6025]

Medical Devices; Neurological Devices; Classification of the Electrical Tongue Nerve Stimulator To Treat Motor Deficits

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 electrical tongue nerve stimulator to treat motor deficits 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 classification of the electrical tongue nerve stimulator to treat motor deficits. We are taking this action because we have determined that classifying the device into class II 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 December 19, 2025. The classification was applicable on March 25, 2021.

FOR FURTHER INFORMATION CONTACT: Ozell Sanders, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4524, Silver Spring, MD 20993–0002, 301–796–3126, *Ozell.Sanders@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the electrical tongue nerve stimulator to treat motor deficits 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.

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 August 4, 2020, FDA received Helius Medical Inc.'s request for De Novo classification of the Portable Neuromodulation Stimulator (PoNS). 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 section 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 March 25, 2021, 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 882.5889.[1] We have named the generic type of device ''electrical tongue nerve stimulator to treat motor deficits,'' and it is identified as a prescription device that consists of a non-implantable apparatus to generate electrical pulses for stimulation of the nerves in the tongue to provide treatment of motor deficits.

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—ELECTRICAL TONGUE NERVE STIMULATOR TO TREAT MOTOR DEFICITS RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.

[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.

TABLE 1—ELECTRICAL TONGUE NERVE STIMULATOR TO TREAT MOTOR DEFICITS RISKS AND MITIGATION MEASURES—Continued

Identified risks to health	Mitigation measures
Thermal, electrical, or mechanical fault, or system malfunction resulting in tissue damage due to overstimulation or thermal injury (*e.g.,* burn/shock) to user.	Electrical, mechanical, and thermal safety testing; Electromagnetic compatibility testing; Battery safety testing; Non-clinical performance testing; Software validation, verification and hazard analysis; and Labeling.
Use error that may result in user discomfort or injury	Labeling.
Device contamination resulting in patient illness	Labeling.
Adverse events involving the mouth, tongue, or gums such as irritation and discomfort.	Labeling.

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.

Under the FD&C Act, submission of a premarket notification under section 510(k) (21 U.S.C. 360(k)) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m). At this time FDA has not made this determination for electrical tongue nerve stimulators to treat motor deficits. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, the electrical tongue nerve stimulator to treat motor deficits is 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 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 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 § 882.5889 to subpart F to read as follows:

§ 882.5889 Electrical tongue nerve stimulator to treat motor deficits.

(a) *Identification.* An electrical tongue nerve stimulator to treat motor deficits is a prescription device that consists of a non-implantable apparatus to generate electrical pulses for stimulation of the nerves in the tongue to provide treatment of motor deficits.

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

(1) Performance data must demonstrate that all patient-contacting components of the device are biocompatible.

(2) Performance data must demonstrate the electromagnetic compatibility, battery safety, and electrical, mechanical, and thermal safety of the device.

(3) Non-clinical performance testing must characterize the electrical stimulation parameters of the device.

(4) Software verification, validation, and hazard analysis must be performed. Software documentation must include an assessment of the impact of threats and vulnerabilities on device functionality and end users as part of cybersecurity review.

(5) Labeling must include:

(i) A detailed summary of the device's technical parameters;

(ii) Instructions for use;

(iii) Cleaning, storage, and charging instructions; and

(iv) Disposal instructions.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–23413 Filed 12–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 58

[TD 10037]

RIN 1545–BQ59

Excise Tax on Repurchase of Corporate Stock; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final rule; correction and correcting amendments.

SUMMARY: This document includes corrections to Treasury Decision 10037 published in the **Federal Register** on Monday, November 24, 2025. Treasury