September 20, 2022

Helius Medical, Inc.
Lawrence Picciano
Vice President Quality and Regulatory
642 Newtown Yardley Road, Suite 100
Newtown, Pennsylvania 18940

Re: DEN200050
Trade/Device Name: Portable Neuromodulation Stimulator (PoNS)
Regulation Number: 21 CFR 882.5889
Regulation Name: Electrical tongue nerve stimulator to treat motor deficits
Regulatory Class: Class II
Product Code: QCF
Dated: August 4, 2020
Received: August 4, 2020

Dear Lawrence Picciano:

This letter corrects our previous classification order, dated March 25, 2021, to correct the regulation name to more accurately describe the target of the electrical stimulation provided by devices of this generic type.

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 Portable Neuromodulation Stimulator (PoNS), a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The PoNS device is indicated for use as a short term treatment of gait deficit due to mild to moderate symptoms from multiple sclerosis and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Portable Neuromodulation Stimulator (PoNS), and substantially equivalent devices of this generic type, into Class II under the generic name electrical tongue nerve stimulator to treat motor deficits.

FDA identifies this generic type of device as:

> **Electrical tongue nerve stimulator to treat motor deficits.** 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.

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 August 4, 2020, FDA received your De Novo requesting classification of the Portable Neuromodulation Stimulator (PoNS). The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Portable Neuromodulation Stimulator (PoNS) 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 Portable Neuromodulation Stimulator (PoNS) 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 to health are adverse tissue reaction, electrical shock (from electrode array), interference with other devices, software malfunction leading to injury or discomfort (e.g., tissue damage due to over-stimulation), hardware malfunction leading to injury or discomfort, use error that may result in user discomfort or injury, device contamination, and irritation, discomfort or adverse events involving the mouth, tongue, or gum. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risk	**Mitigation Measures**
Adverse tissue reaction	Biocompatibility evaluation
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 (EMC) testing Battery safety testing Non-clinical performance testing Software validation, verification & hazard analysis 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

In combination with the general controls of the FD&C Act, the electrical tongue nerve stimulator to treat motor deficits is subject to the following special controls:

(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:
   a) A detailed summary of the device's technical parameters;
   b) Instructions for use;
   c) Cleaning, storage, and charging instructions; and
   d) Disposal instructions.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

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.

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); 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 Ozell Sanders at 301-796-3126.

Sincerely,

David P. Mc Mullen -S

David McMullen, MD
Director
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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