May 8, 2026

Neurovalens Limited
Jason McKeown, M.D., Ph.D.
CEO
8 Carmagrim Road
Portglenone, BT44 8BP
United Kingdom

Re: DEN250013
Trade/Device Name: Modius Spero
Regulation Number: 21 CFR 882.5807
Regulation Name: Transcranial nerve stimulation device for the treatment of post-traumatic stress disorder associated symptoms
Regulatory Class: Class II
Product Code: SHX
Dated: April 16, 2025
Received: April 16, 2025

Dear Dr. Jason McKeown:

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 Modius Spero, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> Modius Spero is a home-use device indicated for the treatment of symptoms associated with post-traumatic stress disorder (PTSD) for use in conjunction with a comprehensive treatment plan under the direction of a healthcare professional, in adults aged 22 and older.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Modius Spero, and substantially equivalent devices of this generic type, into Class II under the generic name transcranial nerve stimulation device for the treatment of post-traumatic stress disorder associated symptoms.

FDA identifies this generic type of device as:

> **Transcranial nerve stimulation device for the treatment of post-traumatic stress disorder associated symptoms**. A transcranial nerve stimulation device for the treatment of post-traumatic stress disorder (PTSD) associated symptoms is a prescription, home-use, externally worn device that applies electrical stimulation to a location on the patient's head. The device is not intended as a stand-alone therapy or to alter usual care treatment.

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 April 16, 2025, FDA received your De Novo requesting classification of the Modius Spero device. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify Modius Spero 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 Modius Spero device 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 and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	Mitigation Measures
Ineffective treatment leading to: • Sustained or worsening of PTSD symptoms • Delayed effective treatment	Clinical performance testing Non-clinical performance testing Software verification, validation, and hazard analysis Electrical, mechanical, and thermal safety testing Electromagnetic compatibility (EMC) testing Use life testing Labeling
Headache/migraine	Clinical performance testing Labeling
Sensory or movement impairment (vision impairment, tinnitus, vertigo)	Clinical performance testing Labeling
Device malfunction leading to injury to patient (e.g., interference, over- or under-stimulation, shock, skin discomfort, burns, pain)	Clinical performance testing Non-clinical performance testing Electrical, mechanical, and thermal safety testing Electromagnetic compatibility (EMC) testing Software verification, validation, and hazard analysis Use life testing Labeling
Adverse tissue reaction	Biocompatibility evaluation

In combination with the general controls of the FD&C Act, the transcranial nerve stimulation device for the treatment of post-traumatic stress disorder associated symptoms is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must evaluate changes in symptoms associated with PTSD (e.g., hyperarousal, sleep disturbance, and intrusion symptoms) and evaluate all adverse effects.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use for the duration of the use life of the device. The technical parameters of the device including waveform, train delivery, maximum output current and voltage, pulse duration, frequency, net charge per pulse, maximum current density, maximum average current, and maximum average power density must be fully characterized and verified.

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

(4) Performance testing must demonstrate electrical safety, mechanical safety, thermal safety, and electromagnetic compatibility of the device in the intended use environment.

(5) Software verification, validation, and hazard analysis must be performed.

(6) The patient and physician labeling for the device must include the following:

    (i) A summary of the clinical performance testing conducted with the device;
    (ii) A statement that the device is not intended as a stand-alone therapy or to alter usual care treatment;
    (iii) A warning that patients should be monitored by their physician for side effects and signs of symptoms worsening;
    (iv) A warning that instructs patients on how to mitigate the risk of anticipated side effects, such as dizziness or headache, and what to do should side effects occur;
    (v) Instructions for use based on the treatment parameters (electrode placement, stimulation parameters, duration and frequency) used in clinical performance testing; and
    (vi) A detailed description of the device technical parameters, including waveform, output mode, pulse duration, frequency, train delivery, maximum charge, explanation of all device outputs, and use life.

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.

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) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification

requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the transcranial nerve stimulation device for the treatment of post-traumatic stress disorder associated symptoms they intend to market prior to marketing the device.

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).

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System Rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Jessica Franklin at Jessica.Franklin@fda.hhs.gov.

Sincerely,

JAY R. GUPTA -S

For Heather Dean, Ph.D.
Acting Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health