August 26, 2024

Neuros Medical, Inc.
Julie Broderick
Regulatory Consultant/Principal Consultant
26800 Aliso Viejo Parkway, Suite 250
Aliso Viejo, California 92652

Re: P230020
Trade/Device Name: Altius® Direct Electrical Nerve Stimulation System
Product Code: SAZ
Filed: June 30, 2023
Amended: July 25, 2023, August 31, 2023, January 29, 2023

Dear Julie Broderick:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Altius® Direct Electrical Nerve Stimulation System. This device is indicated as an aid in the management of chronic intractable phantom and residual lower limb post-amputation pain in adult amputees. Based upon the information submitted, the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to all other applicable requirements, including those governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at five years for the Altius Implantable Pulse Generator (IPG) and port plug, three years for the Altius cuff electrode.

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and must include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, under 21 CFR 814.82(a)(9), the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

You have agreed to provide the following non-clinical information in a PMA report, which may be followed by a PMA supplement where applicable.

1. Human Factors (HF) Analysis and Validation Testing

   Neuros Medical will provide a human factor engineering (HFE) and usability engineering (UE) analysis and validation testing in a PMA report, which may be followed by a PMA supplement where applicable. The HFE/UE analysis and testing will be designed using well established methods, such as those described in the FDA guidance document “Applying Human Factors and Usability Engineering to Medical Devices” (https://www.fda.gov/media/80481/download) issued on February 3, 2016, and will, include, but is not limited to:

   a. Identification of anticipated use-related hazards and initially unanticipated use-related hazards and determine how hazardous use situations occur (see section 6 of the HFE/UE guidance document referenced above for additional information). Outcomes of these analyses will include comprehensive identification and categorization of user tasks, leading to a list of critical tasks. The results of these analyses and evaluations will be used to inform your risk management efforts and development of the protocol for the human factors validation testing described in part C below. AND

   b. Development and application of measures to eliminate or reduce use-related hazards that could result in harm to the patient or the user (see section 7 of the HFE/UE guidance document referenced above for additional information). Unless design modifications and/or manufacturing process changes can completely remove the possibility of a use error, protective measures such as labeling and training (if applicable) will be modified to address use-related hazards. If no other options are available, users will at least be given sufficient information to understand and avoid the hazard. AND

   c. Demonstration that the final device user interface design and labeling supports safe and effective use by conducting HFE/UE validation testing (see section 8 of the HFE/UE guidance document referenced above for additional information). The validation testing will have an adequate sample size for each of the distinct user population, and the test participants should be representative of the same user population. Specifically, the HF validation testing will assess performance of all critical tasks during simulated use of the final subject device involving a minimum of 15 representative users per distinct user group residing in the US or US Territories (Puerto Rico, Guam, and the US Virgin Islands). Data collection will include, but not be limited

to, observational data, knowledge task data, and interview data.

Neuros Medical will provide an HFE/UE report that includes the contents outlined in Appendix A of the HFE/UE guidance document referenced above.

2. Labeling

   Neuros Medical will include the following disclaimer prominently in all their labeling documentation (e.g., user manuals, brochures, instructions for use, websites, device packaging, etc.) prior to marketing the subject device: *Although FDA has determined that the probable benefits outweigh the probable risks, there remains some uncertainty regarding the manufacturer's human factors engineering (HFE) and usability engineering (UE) analysis and validation testing. As a condition of approval, FDA is requiring the manufacturer to provide an HFE/UE analysis and validation testing and recommending that this analysis and testing is designed using the FDA's 2016 guidance document "Applying Human Factors and Usability Engineering to Medical Devices" (https://www.fda.gov/media/80481/download).*

   This labeling statement can be removed once the HF/U study results, and any changes necessary to address those results, have been reviewed and approved by FDA in a PMA supplement.

3. Timeline

   Neuro Medical will provide the additional information outlined above to satisfy the Conditions for Approval for FDA to review through a separate PMA report, (which may be followed by a PMA supplement where applicable) within 12 months of the approval (APPR) letter. The specific timeline is as follows:

   - Condition #1
     - Submit part A within 30 days of the approval letter
     - Submit part B and the complete proposed protocol for the HFE/UE validation testing (part C) within 60 days of FDA concurrence with part A
     - Submit part C within 12 months of the approval letter
   - Condition #2
     - The labeling disclaimer will be added prior to marketing the subject device.

Be advised that failure to comply with any post-approval requirement, including HFE/UE analysis and validation testing, labeling, and timeline outlined above, constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 21 CFR 814.46(a)(2).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI

website available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. Additional information about changes that may require a PMA supplement are provided in the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" https://www.fda.gov/media/81431/download.

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production and process controls (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or post-marketing safety reporting (21 CFR Part 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems and on combination product post-marketing safety reporting is available at https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products.

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR Part 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve

your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found at https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Chun (Phoebe) Xu, PhD at Chun.Xu@fda.hhs.gov.

Sincerely,

David P. Mc Mullen -S

Digitally signed by David P. Mc Mullen -S
Date: 2024.08.26 16:06:42 -04'00'

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