November 20, 2020

Neuronetics, Inc.
Gary Johnson
Director, Regulatory Affairs
3222 Phoenixville Pike
Malvern, PA 19355

Re: K201158
Trade/Device Name: NeuroStar Advanced Therapy
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulation system
Regulatory Class: Class II
Product Code: OBP
Dated: October 22, 2020
Received: October 23, 2020

Dear Gary Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Pamela Scott
Assistant 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
N/A K201158

Device Name
NeuroStar Advanced Therapy

Indications for Use *(Describe)*
NeuroStar Advanced Therapy is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

NeuroStar Advanced Therapy System

510(k) Owner: Neuronetics, Inc.
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Date Prepared: April 28, 2020

Proprietary Name: NeuroStar Advanced Therapy System

Common Name: Transcranial Magnetic Stimulator

Classification Name: Repetitive Transcranial Magnetic Stimulation Device
21 CFR 882.5805, Product Code OBP

Predicate Device: NeuroStar Advanced Therapy System
(K161519)

Reference Device: MagVita TMS Therapy System w/ Theta Burst Stimulation
(K173620)

Device Description

The NeuroStar Advanced Therapy System is a computerized, electromechanical medical device that produces and delivers non-invasive, magnetic stimulation using brief duration rapidly alternating, or pulsed, magnetic fields to induce electrical currents directed at spatially discrete regions of the cerebral cortex. This method of cortical stimulation by application of brief magnetic pulses to the head is known as Transcranial Magnetic Stimulation (TMS).

NeuroStar Advanced Therapy is a non-invasive tool for the stimulation of cortical neurons for the treatment of adult patients with Major Depressive Disorder (MDD) who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode. NeuroStar Advanced Therapy is used for patient treatment by prescription only under the supervision of a licensed physician and can be used in both inpatient and outpatient settings including physician's offices, clinics, and hospitals.

NeuroStar Advanced Therapy uses a well-understood property of physics regarding the law of electromagnetic induction, which states that a time-varying or moving magnetic field will induce an electric current in an adjacent conductive substance with the electric current traveling in a direction perpendicular to the motion of the magnetic field. NeuroStar Advanced Therapy uses a generated magnetic field as a vector for delivering an electrical current to a target conductor of interest, which in therapeutic application, is the brain. By

using this method of delivering electrical current to the brain the electrical current produced in the brain can be delivered in an anatomically focused manner at discrete cortical areas of interest and can avoid areas of the brain that are not relevant for its therapeutic actions.

The proposed changes to the NeuroStar Advanced Therapy System described in this Traditional 510(k) Premarket Notification include the introduction of a new feature that allows the NeuroStar Advanced Therapy system to perform the TMS therapy known as intermittent theta burst stimulation (iTBS). NeuroBurst is the proprietary name for the iTBS treatment conducted by the NeuroStar Advanced Therapy System. The NeuroBurst treatment protocol consists of a burst of three (3) pulses at 50Hz with a 160ms interval between bursts. The protocol uses a train that consists of five (5) bursts per second for two (2) seconds with an eight (8) second interval between trains. A treatment session lasts for 20 trains or 3.3 minutes.

The NeuroStar Advanced Therapy System is an integrated system consisting of a combination of the following components:

- Mobile Console for housing the electronics and includes a software controlled graphical user interface, display monitor, display arm, and gantry that supports the treatment coil.
- Ferromagnetic Coil for delivering treatment.
- Head Support System for positioning the treatment coil and includes a laser-guided alignment system.
- Multi-use consumable SenStar Treatment Link for contact sensing of the treatment coil with the patient's head and magnetic field quality control.
- TrakStar Patient Data Management System for recording patient data and includes a stand-alone computer and data management software.

Intended Use / Indications for Use

NeuroStar Advanced Therapy is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Technological Characteristics

The key technological characteristics of the NeuroStar Advanced Therapy System are substantially equivalent to NeuroStar TMS Therapy System as described in submission K161519 (predicate device) regarding:

- Indications for Use
- Technological characteristics, including design for delivery of TMS
- Principles of operation and performance specifications
- Materials and standards

The proposed changes to the NeuroStar Advanced Therapy System include a modification to the power module subsystem, which was updated with a new micro-controller due to obsolescence. The updated micro-controller is provided by the same manufacturer and is a drop-in replacement for the current micro-controller. Firmware was also updated to support the micro-controller hardware component change. All other materials and the process for delivery of TMS are the same as the predicate device.

Both the NeuroStar Advanced Therapy System and the predicate device consist of the same components, which include: the mobile console with software, treatment coil, head support system, multi-use consumable, and patient data management system. Both devices utilize the same operational procedures for system setup, patient preparation, motor threshold determination, treatment coil positioning, and patient treatment. Both devices use the same principles of operation to apply TMS treatment at a defined intensity as repetitive pulse trains delivered as brief rapidly alternating magnetic fields to induce electrical currents to the prefrontal cortex. Both devices use the same system performance specifications to ensure the device performs as intended for the same indications for use. The only difference in technological characteristics between the NeuroStar Advanced Therapy system and predicate device is the NeuroBurst treatment specific aspects and stimulation parameters, which differ from the standard treatment stimulation parameters of the predicate device only in terms of pulse train duration, intertrain interval, and pulses per treatment.

The standard treatment protocol for the NeuroBurst treatment is similar to the treatment protocol of the MagVita TMS Therapy System w/ Theta Burst Stimulation (reference device). The iTBS protocol of the reference device has been shown to produce equally effective clinical results as compared to the standard-of-care TMS therapy protocol for the treatment of adult patients with Major Depressive Disorder. Since the use of iTBS treatment was cleared by the FDA for the reference device under submission K173620 and given that the NeuroStar Advanced Therapy system and reference device share the same intended use and similar technological characteristics, the safety and effectiveness of the NeuroBurst treatment can be demonstrated by comparison of the key performance specifications between the subject device and the reference device. This comparison supports the conclusion that the iTBS treatment of the reference device and the NeuroBurst treatment of the NeuroStar Advanced Therapy System are the same and as such the NeuroBurst treatment is an appropriate treatment for Major Depressive Disorder in adult patients.

The methods for evaluating the differences in technological characteristics between the NeuroStar Advanced Therapy System and predicate device supports the conclusion that the safety and effectiveness of the NeuroStar Advanced Therapy System are substantially equivalent to that of the predicate device cleared under submission K161519 and that the changes to the NeuroStar Advanced Therapy System do not raise new questions of safety or effectiveness compared to the predicate device.

Non-clinical Performance Data

The non-clinical performance data included in this Traditional 510(k) Premarket Notification address the performance data recommendations and relevant mitigation measures outlined in the Agency's special controls guidance entitled *"Class II Special Controls Guidance Document for Repetitive Transcranial Magnetic Stimulation (rTMS) Systems"* issued on July 26, 2011.

Testing was performed according to the Special Requirements Document to show Substantial Equivalence to the predicate device. NeuroStar testing showed substantially

equivalent results to the predicate device for magnetic field characteristics such as special distribution, magnetic field strength gradients, output waveform, and linear output level.

An electro-magnetic model of both system coils was created to compare the resultant magnetic fields produced by a 1 SMT pulse. The modules and test parameters were identical with the exception of the specific mechanical construction details between the two coils. Plots of the spatial extent of the magnetic field showed substantial equivalence between the NeuroStar and predicate treatment coils.

In addition, System verification testing of the NeuroStar Advanced Therapy System has been tested to verify system performance to specifications. This includes testing of the NeuroBurst stimuli intensity which was found to meet specification and is substantially equivalent to the predicate device.

Risk assessment was applied throughout the product development lifecycle process in accordance with the requirements set forth under the Agency recognized consensus standards ISO 14971:2007 and IEC 62304:2015. The results of the comprehensive risk analysis for the device indicate that there are no new hazards, harms, or safety risks introduced when compared to the predicate device. The NeuroStar Advanced Therapy System is in compliance with the requirements set forth under the Agency recognized consensus standards 60601-1-2:2014 Edition 4.0 and IEC 60601-1:2005 AMD1:2012 Edition 3.1 for electromagnetic compatibility (EMC) and electrical safety.

The device and software specifications, verification testing, validation testing, and risk management activities demonstrate that the NeuroStar Advanced Therapy System meets performance and functionality requirements and performs as intended without raising new questions of safety or effectiveness when compared to the predicate device. Performance testing was conducted to ensure that the NeuroStar Advanced Therapy System can perform NeuroBurst treatment and that system functionality had not been adversely impacted by the introduction of the new feature.

The clinical performance of iTBS treatment of the predicate device looked at stimuli of equal intensity and that the three stimuli within a burst are kept constant. Performance testing of the NeuroStar demonstrates that the intensity of the individual stimuli within a NeuroBurst treatment burst are of virtually equal intensity between bursts, which provides a consistent treatment dose that is clinically effective for NeuroBurst treatment when used to treat patients.

The non-clinical performance data supports the conclusion that the performance, functionality, safety, and effectiveness of the subject device are substantially equivalent to that of the predicate device cleared under submission K161519 and that the changes to the NeuroStar Advanced Therapy System do not raise new questions of safety or effectiveness compared to the predicate device.