DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 10, 2016

Neuronetics, Inc.
Judy Ways
Vice President, Regulatory Affairs and Quality Assurance
3222 Phoenixville Pike
Malvern, Pennsylvania 19355

Re: K160703
Trade/Device Name: Neurostar TMS Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: March 11, 2016
Received: March 14, 2016

Dear Judy Ways:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.06.10 10:29:25 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160703

Device Name
NeuroStar TMS Therapy System

Indications for Use *(Describe)*
The NeuroStar TMS Therapy System 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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NEURONETICS

510(k) Summary

NeuroStar® TMS Therapy System

510(k) Owner: Neuronetics, Inc.
3222 Phoenixville Pike
Malvern, PA 19355
Phone: 610-640-4202
Fax: 610-640-4206

Company Contact: Judy P. Ways, Ph.D.
Vice President,
Regulatory Affairs and Quality Assurance
Neuronetics, Inc.
3222 Phoenixville Pike
Malvern, PA 19355
Phone: 610-981-4107
Fax: 610-640-4206

Date Prepared: 11 March 2016

Proprietary Name: NeuroStar® TMS Therapy System

Common Name: Transcranial Magnetic Stimulator

Classification Name: Transcranial Magnetic Stimulator for Treatment of Major Depressive Disorder [21 CFR 882.5805, Product Code OBP]

Predicate Device: NeuroStar TMS Therapy® System [K133408]

Device Description:

The NeuroStar TMS Therapy System is a computerized, electromechanical medical device that produces and delivers non-invasive, magnetic stimulation using brief duration (185 µsec nominal) 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 or TMS. NeuroStar TMS 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 as described under Intended Use. The NeuroStar System is used for patient treatment by prescription only under the supervision of a licensed physician. It can be used in both inpatient and outpatient settings including physician's offices and clinics, and hospitals.

The NeuroStar TMS Therapy System is an integrated system consisting of a combination of hardware, software, accessories and consumable supplies. It includes a Mobile Console which houses the electronics, includes a software controlled graphical user interface, and gantry that supports the Treatment Coil. The ferromagnetic Treatment Coil delivers NeuroStar TMS Therapy®. The Head Support System provides accurate positioning of the Treatment Coil using a laser-guided alignment system. The SenStar® Connect is a non-sterile, multi-use consumable which is applied to the Treatment Coil, provides contact sensing to monitor contact of the treatment coil with the patient's head throughout a treatment session, quality control by monitoring the magnetic field level prior to patient treatment and provides surface field cancellation to reduce stimulation of the scalp. The TMS TrakStar™ practice data management system consists of a stand-alone computer and data management software that facilitates recording and retrieval of patient and treatment information and communication of data among multiple NeuroStar TMS Systems.

Intended Use:

The NeuroStar TMS Therapy System 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 and Substantial Equivalence:

The subject device, NeuroStar TMS System, has the following similarities to the predicate TMS device (NeuroStar TMS Therapy System, K133408):

- Principles of operation
- Design for delivery of Transcranial Magnetic Stimulation (TMS)
    - Output stimulation parameters (pulse width, frequency range, pulse interval range, etc.)
- Materials

The change for the NeuroStar TMS Therapy System is a modification to the labeling of the device to allow a range of inter-train intervals from 11 to 26 seconds, rather than the fixed 26 second duration, which will allow a reduction in treatment time from 37.5 minutes to a minimum of 18.8 minutes. The change is intended to address physician and patient requests for a reduced treatment time due to issues of comfort and convenience to improve access. The proposed change is supported by information submitted in this premarket notification and with the following rationale:

1. **Device is substantially equivalent to the FDA-cleared NeuroStar TMS Therapy System**: The NeuroStar TMS Therapy System that is the subject of the premarket notification is the same device cleared by the FDA under DEN070003/K061053, K083538, K130233 and K133408. This change remains within the existing product specification for inter-train interval (range 10-60 seconds for > 1 pulse per second).
2. **Device new clinical data supports the revised labeling:** New clinical data obtained from a review of clinical trials conducted with the NeuroStar TMS Therapy System and reference

TMS devices demonstrate the use of inter-train intervals in the proposed range from 11 to 26 seconds does not impact the safety and efficacy of the NeuroStar TMS Therapy System for its Intended Use.

Changes to the device labeling include revised instructions for use to include a range of inter-train intervals from 11 to 26 seconds depending on physician and patient preference. No other changes are made to the device or product labeling. Therefore, the NeuroStar TMS Therapy System with this change to the product labeling is substantially equivalent to the predicate device.

Clinical Performance:

A database search was conducted to identify human studies evaluating TMS and variations in inter-train interval. This analysis encompassed 79 studies and research outcomes on 3359 subjects, among whom 2162 subjects were exposed to active TMS treatment. Data from these studies were used to analyze the safety and effectiveness of TMS delivered using varying TMS treatment parameters, particularly varying inter-train intervals. The analysis of effectiveness was conducted using the results of 44 studies (a total of 50 active treatment arms) where there was complete information to identify the TMS treatment parameter set used and the clinical outcome for the primary efficacy measure. In addition to reviewing the data from clinical trials, the evidence summarized in four peer-reviewed meta-analyses of the efficacy of TMS for the treatment of major depressive disorder was also examined. Eleven clinical studies utilized the NeuroStar TMS Therapy System or progenitor iron-core devices and encompassed 1069 subjects, among whom 770 subjects received active TMS. The remaining studies used reference TMS devices. This analysis showed that variations across the range of inter-train intervals used within the reported treatment parameter sets do not impact TMS efficacy.

For safety analysis, when provided, adverse events using the verbatim terms used in the reference were aggregated. The sporadic incidence of seizure was also evaluated. These data represent summary evidence from 61 studies, comprising 67 active treatment arms among 2836 subjects. This analysis showed that there is no evidence to indicate that the risk of inadvertent seizure or the pattern of common adverse events reported for TMS varies in a systematic manner across the range of inter-train intervals used within the reported treatment parameter sets.

The NeuroStar TMS Therapy System that is the subject of this premarket 510(k) notification is the same (substantially equivalent) device cleared by the FDA under DEN070003/K061053, K083538, K130233 and K133408. New clinical data from a literature review of clinical trials conducted for the NeuroStar TMS Therapy System and reference TMS devices demonstrate that the revised inter-train interval range does not impact the safety and efficacy of the NeuroStar TMS Therapy System for its indicated use.

[1]The NeuroStar ® and NeuroStar TMS Therapy® are registered trademarks of Neuronetics, Inc. TMS Therapy™ and NeuroStar TrakStar™ are trademarks of Neuronetics, Inc.