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

September 11, 2016

Neuronetics, Inc.
Judy Ways, Ph.D.
V.P., Regulatory Affairs and Quality Assurance
3222 Phoenixville Pike
Malvern, Pennsylvania 19355

Re: K161519
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: August 12, 2016
Received: August 15, 2016

Dear Dr. 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: 2016.09.11 12:04:45 -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)*
K161519

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.
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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: 12 August 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.

Indication/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 NeuroStar TMS Therapy System 3.0 is substantially equivalent to the predicate device (NeuroStar TMS Therapy System, K133408, K160703) for:

- Indication for Use
- Principles of Operation
- Design for Delivery of Transcranial Magnetic Stimulation
- Performance Specifications
- Materials
- Standards

The NeuroStar TMS Therapy System 3.0 modifications from the predicate device include enhanced thermal performance of the system, improved ergonomics and reliability in handling of the Treatment Coil, and an improved user work flow for the recording of treatment information to the NeuroStar software. Software password security has been enhanced in NeuroStar 3.0 and the TrakStar data management system.

Table 1 Performance Specifications for NeuroStar System 3.0 and Predicate Device

Device Feature	NeuroStar TMS System (K133408)	NeuroStar TMS Therapy System 3.0
Treatment Level Range	0.22 SMT to 2.11 SMT (calibrated linear output)	0.22 SMT to 2.08 SMT (calibrated linear output)
Induced Electric Field at 2 cm at 1.0 SMT	135 V/m (nominal)	135 V/m (nominal)
%MT Range	80% to 140% MT	25% to 140% MT
Pulses per Second Range	1 - 30 pps for treatment 0.1 - 0.3 pps for MT determination	1 - 30 pps for treatment 0.1 - 0.3 pps for MT determination
Stimulation Time Range (Pulse Train Duration)	1 - 600 Seconds for 1 pps 1 - 20 Seconds for >1 pps	1 - 600 Seconds for 1 pps 1 - 20 Seconds for >1 pps
Inter-Train Interval Range	0 - 600 Seconds for 1 pps 10 - 60 Seconds for > 1 pps	0 - 600 Seconds for 1 pps 10 - 60 Seconds for > 1 pps
Pulse Type	Biphasic Sinusoid	Biphasic Sinusoid
Pulse Width	185µS (nominal)	185µS (nominal)
Pulses per Treatment Session	Maximum: 5000 Nominal: 3000	Maximum: 5000 Nominal: 3000
Coil Type	Ferromagnetic, Iron Core	Ferromagnetic, Iron Core with internal cooling fan
Coil Positioning System	Integrated into Head Support System, Laser-Aided Coil Placement	Integrated into Head Support System, Laser-Aided Coil Placement
Treatment Quality Features	Magnetic Field Level Detection Coil Contact Sensing	Magnetic Field Level Detection Coil Contact Sensing

Bench Performance Testing:

The following performance tests were conducted to demonstrate the substantial equivalence of NeuroStar 3.0 to the predicate NeuroStar TMS Therapy System.

- Magnetic field mapping in 3-dimensions, spatial and temporal characteristics, and pulse sequence timing
- Coil positioning accuracy for MT, MT level and treatment location

The following additional tests were conducted to demonstrate that NeuroStar 3.0 meets performance specifications.

- NeuroStar system hardware and software unit, system and user story testing
- Usability engineering testing
- Electrical safety testing to IEC 60601-1:2005 and Electromechanical Compatibility (EMC) testing to IEC 60601-1-2:2007, Third Edition

Verification and validation testing demonstrated that the changes to NeuroStar 3.0 do not substantially modify the performance of the device. Therefore, differences in specifications, design, materials and manufacturing process for the NeuroStar TMS System 3.0 do not raise new questions of safety and effectiveness of the device for its indicated use. Labeling changes for NeuroStar 3.0 reflect the device changes and the labeling is otherwise the same as for the predicate device, NeuroStar TMS Therapy System (K133408/K160703).

The NeuroStar TMS Therapy System 3.0 complies with the requirements for TMS systems as defined in the FDA's "*Class II Special Controls Guidance Document for Repetitive Transcranial Magnetic Stimulation (rTMS) System*", dated 26 July 2011. It complies with the same medical device performance standards applied to the commercial NeuroStar System.

Based on this information, the NeuroStar TMS Therapy System 3.0 is substantially equivalent to the predicate device, NeuroStar TMS Therapy System cleared by the FDA under K133408 and K160713.

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