K130233

NEURONETICS

510(k) Summary
NeuroStar® TMS Therapy System

APR 30 2013

510(k) Owner: Neuronetics, Inc.
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Date Prepared: 30 April 2013

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 [K061053/K083538]

Device Description: The NeuroStar TMS Therapy System is a computerized, electromechanical medical device that produces and delivers non-invasive, magnetic stimulation using brief duration (~200 μsec) 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.

The NeuroStar TMS System 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 TMS 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 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 the TMS Therapy™. The Head Support System provides accurate positioning of the Treatment Coil using a laser-guided alignment system. A single-use device, the SenStar® Treatment Link, 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, surface field cancellation to reduce stimulation of the scalp, and acts as a hygiene barrier from patient to patient. The TMS TrakStar (previously known as Practice Data Management System - PDMS) 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

NeuroStar TMS Therapy is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from one prior antidepressant medication at or above the minimal effective dose and duration 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, K061053/K083538):

- Indications for use
- Principles of operation
- Design for delivery of Transcranial Magnetic Stimulation (TMS)
- Materials
- Shelf life, and packaged using the same materials and processes.

The proposed change, which is the subject of this 510(k), is a labeling change to the prescribing statement to comply with the FDA's Class II Special Controls Guidance for Repetitive Transcranial Magnetic Stimulation (rTMS) Devices (26 July 2011). No other changes are made to the device or labeling. Therefore, the NeuroStar TMS Therapy System with the change proposed in the 510(k) is substantially equivalent to the predicate device.

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

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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

April 30,2013

Neuronetics, Inc.
c/o Judy P. Ways, Ph.D.
Vice President, Regulatory Affairs and Quality Assurance
31 General Warren Boulevard
Malvern, PA 19355

Re: K130233
NeuroStar TMS Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulator for Treatment of Major Depressive Disorder
Regulatory Class: Class II
Product Code: OBP
Dated: January 29, 2013
Received: January 30, 2013

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K130233

Device Name: NeuroStar TMS Therapy System

Indications For Use:

The NeuroStar TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from one prior antidepressant medication at or above the minimal effective dose and duration in the current episode.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number __K130233_____