

NEURONETICS

K063538

510(k) SUMMARY

NEUROSTAR TMS THERAPY[®] SYSTEM¹

510(k) Owner:

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DEC 16 2008

Company Contact:

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Date Prepared:

28 November 2008

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 System² [K061053]

Device Description:

The NeuroStar TMS System is a computerized, electromechanical medical device that produces and delivers non-invasive, magnetic stimulation using brief duration (~200 μ sec) 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 peak magnetic field strength achieved with each pulse is approximately 1.5 Tesla.

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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. The NeuroStar TMS System is used for patient treatment by prescription only under the supervision of a licensed psychiatrist. It can be used in both inpatient and outpatient settings including psychiatrist's offices and clinics, psychiatric hospitals, and general medical/surgical hospitals with psychiatric units.

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, mechanically supports the ferromagnetic Treatment Coil and includes a software controlled graphical user interface, a ferromagnetic Treatment Coil to deliver TMS Therapy, a Head Support System for accurate coil positioning, and a single use device (SenStar® Treatment Link) placed on the face of the coil to reduce local scalp stimulation, to provide feedback to the operator regarding contact of the coil with the patient's head, and to verify the applied field strength. A separate Practice Data Management System (PDMS) allows and facilitates recording and retrieval of patient and treatment information and communication of data among multiple NeuroStar TMS System units.

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 NeuroStar TMS Therapy System with Class 1 laser positioning aid utilizes a Class 1 laser for positioning and registration of the patient's head in the Head Support System prior to coil positioning for Motor Threshold (MT) determination and TMS treatment. The Class 1 laser positioning aid provides for ease of use during head positioning and registration as compared to the use of plastic positioning pointers in the predicate device. The use of the Class 1 laser positioning aid does not substantially change the process of patient positioning for NeuroStar TMS Therapy and provides equivalent accuracy in coil placement for MT determination and TMS treatment as shown by verification and validation testing.

The Class 1 laser positioning aid consists of a laser diode, line generating lens, printed circuit board and 1.5V AA battery. The

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optical components are cemented in place and mechanically captured with a non-removable bezel. The circuitry regulates the laser diode current based on measured output and incorporates a timing circuit that ensures that the laser diode is turned off after a maximum of 45 seconds. There are no user or service adjustable components; the only required maintenance is replacement of the battery on an annual basis during the required system preventative maintenance visit which is performed by a trained service technician. The only laser radiation that is accessible during use or service is the primary output beam which meets Class 1 requirements.

Laser certification and identification labels and additional Instructions for Use are provided as required for a Class 1 laser.

Based on risk analysis and performance testing, the NeuroStar TMS Therapy System with Class 1 laser positioning aid raises no new questions of safety and efficacy and is substantially equivalent to the predicate device.

Performance Testing

The NeuroStar TMS Therapy System with Class 1 laser positioning aid was designed in conformity with design controls. Design verification tests were performed as based on a Failure Modes and Effects Analysis (FMEA). The accuracy of the Class 1 laser positioning aid was verified to meet design specifications (Test Report 80-80095-001). Its utility in treatment coil positioning and equivalence to the predicate device in determination of MT and TMS treatment locations was demonstrated (Test Report 80-80095-000).

The laser is Class 1 according to IEC 60825-1 and complies with FDA Laser Notice No. 50 (issued 24 June 2007). The NeuroStar TMS Therapy System including the laser assembly complies with all applicable sections of UL/CSA/EN60601-1 for electrical safety.

Based on performance testing, the NeuroStar TMS Therapy System with Class 1 laser positioning aid is as safe, as effective, and performs as well as the predicate device with enhanced ease of use in patient positioning.

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

² Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without premarket approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation [42 Fed. Reg. 42,520 et seq. (1977)].



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Neuronetics, Inc.
% Judy P. Ways, Ph.D.
Vice President
Regulatory Affairs and Quality Assurance
One Great Valley Parkway, Suite 2
Malvern, Pennsylvania 19355

DEC 16 2008

Re: K083538
Trade/Device Name: NeuroStar TMS Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulator for treatment of major depressive disorder
Regulatory Class: II
Product Code: OBP
Dated: November 28, 2008
Received: November 28, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: NeuroStar TMS Therapy System

Indications for Use:

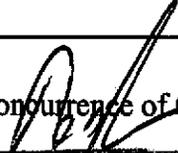
The NeuroStar TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from one prior antidepressant medication at or above the minimal effective dose and duration in the current episode.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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


Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number 16083536