DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

MAR 23 2011

Re: K061053; NeuroStar® TMS System
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 882.5805
Classification: II
Product Code: OBP

Dear Dr. Ways:

This letter corrects our classification letter of October 7, 2008.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation Petition (de novo) for classification of the NeuroStar® TMS System as a prescription device under 21 CFR Part 801.109 that 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. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the NeuroStar® TMS System, and substantially equivalent devices of this generic type into class II under the generic name, Repetitive Transcranial Magnetic Stimulation (rTMS) System.

FDA identifies this generic type of device as:

> A repetitive transcranial magnetic stimulation (rTMS) system is an external device that delivers transcranial repetitive pulsed magnetic fields of sufficient magnitude to induce neural action potentials in the prefrontal cortex to treat the symptoms of major depressive disorder (MDD) without inducing seizure in patients who have failed at least one antidepressant medication and are currently not on any antidepressant therapy.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, with in 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On May 24, 2007, FDA filed your petition requesting classification of the NeuroStar® TMS System into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on April 26, 2007 automatically classifying the NeuroStar® TMS System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. To classify the NeuroStar® TMS System into class I or II, it is necessary that the proposed class has sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, FDA has determined that the NeuroStar® TMS System 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 can be classified in class II with the establishment of special controls for class II. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type.

Risks involved with the use of the device and their mitigation include:

Identified Risk	Mitigation Measures
Usage outside of labeled patient population	Clinical Testing Labeling
Ineffective Treatment	Nonclinical Analysis and Testing Software Life Cycle and Risk Management Animal Testing Clinical Testing Labeling
Seizure	Nonclinical Analysis and Testing Animal Testing Clinical Testing Labeling
Scalp discomfort, scalp burn, or other adverse effects	Nonclinical Analysis and Testing Software Life Cycle and Risk Management Animal Testing Clinical Testing Labeling
Magnetic field effects on functioning of other medical devices	Non-clinical Analysis and Testing Labeling
Adverse Tissue Reaction	Biocompatibility
Hazards Associated with Electrical Equipment	Electrical Equipment Safety Labeling
Hazards caused by Electromagnetic Interference and Electrostatic Discharge Hazards	Electromagnetic Compatibility Labeling
Hearing Loss	Labeling

In addition to the general controls of the act, the NeuroStar® TMS System is subject to the following categories of special controls: device description, nonclinical analysis and testing, biocompatibility, electrical equipment safety, electromagnetic compatibility, wireless technology, software validation, clinical information and labeling. Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the act. Thus, persons who intend to market this device type must submit to FDA a premarket notification submission containing information on the rTMS system they intend to market prior to marketing the device and receive clearance to market from FDA.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the de novo, subject to the general control provisions of the act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Ann H. Costello Ph.D., D.M.D. at 301-776-6493.

Sincerely yours,

Jonette Foy, Ph.D.
Acting Deputy Director
for Science and Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health