DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 13, 2013

eNeura Therapeutics LLC
c/o Mr. Larry Getlin
Regulatory Consultant
2690 Pheasant Road
Orono, MN 55331

Re: K130556
Cerena Transcranial Magnetic Stimulator
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 882.5808
Regulation Name: Transcranial Magnetic Stimulator for Headache
Regulatory Classification: Class II
Product Code: OKP
Dated: March 1, 2013
Received: March 5, 2013

Dear Mr. Getlin:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Cerena Transcranial Magnetic Stimulator, a prescription device under 21 CFR Part 801.109 that is indicated for the acute treatment of pain associated with migraine headache with aura. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Cerena Transcranial Magnetic Stimulator, and substantially equivalent devices of this generic type, into class II under the generic name, Transcranial Magnetic Stimulator for Headache.

FDA identifies this generic type of device as:

> **Transcranial Magnetic Stimulator for Headache.** A transcranial magnetic stimulator device for headache is a device that delivers brief duration, rapidly alternating, or pulsed, magnetic fields that are externally directed at spatially discrete regions of the brain to induce electrical currents for the treatment of headache.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C 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 FD&C 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 FD&C Act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 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 March 5, 2013, FDA received your *de novo* requesting classification of the Cerena Transcranial Magnetic Stimulator into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Cerena Transcranial Magnetic Stimulator into class I or II, it is necessary that the proposed class have 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 *de novo* request, FDA has determined that the Cerena Transcranial Magnetic Stimulator indicated for the acute treatment of pain associated with migraine headache with aura 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. The identified risks and mitigation measures with the device type are summarized in Table 1.

Table 1 - Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Method
Failure to identify correct population	Clinical testing Labeling
Ineffective treatment	Clinical testing Non-Clinical Testing Software Verification, Validation, and Hazard Analysis Labeling
Risk of seizure	Clinical Testing Non-Clinical Testing Labeling
Scalp discomfort, scalp burn, dizziness, nausea, or other adverse effects	Clinical testing Non-Clinical Testing Thermal Safety Software Verification, Validation, and Hazard Analysis Labeling
Adverse tissue reaction	Biocompatibility Labeling
Electrical shock, burn	Electrical Equipment Safety Thermal Safety Labeling
Interference with other electrical equipment	Electromagnetic Compatibility Labeling
Noise Irritation and Hearing Loss	Non-Clinical Testing Labeling

In combination with the general controls of the FD&C Act, the Transcranial Magnetic Stimulator for Headache is subject to the following special controls:

1. Appropriate analysis/testing must demonstrate electromagnetic compatibility (EMC), electrical safety, and thermal safety.
2. Appropriate verification, validation, and hazard analysis must be performed on the device software and firmware.
3. The elements of the device that contact the patient must be assessed to be biocompatible.
4. Non-clinical testing data must demonstrate that the device performs as intended under anticipated conditions of use. This includes full characterization of the magnetic pulse output and resulting magnetic field map. This also includes characterization of the sound level of the device during use.
5. Clinical testing must demonstrate that the device is safe and effective for treating headache in the indicated patient population.
6. The physician and patient labeling must include the following:
    a. A summary of the clinical performance testing, including any adverse events and complications.

b. The intended use population in terms of the types of headaches appropriate for use with the device.
c. Information on how to report adverse events and device malfunctions.
d. A diagram or picture depicting the proper placement of the device on the user.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C 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 FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Transcranial Magnetic Stimulator for Headache 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* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Michael Hoffmann at 301-796-6476.

Sincerely yours,

Jonette R. Foy -S

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