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

August 23, 2016

Eneura Inc
% Mr. Larry Getlin
Regulatory Consultant for Eneura Inc
Larry W. Getlin
2690 Pheasant Road
Orono, Minnesota 55331

Re: K161663
Trade/Device Name: sTMS Mini
Regulation Number: 21 CFR 882.5808
Regulation Name: Transcranial magnetic stimulator for headache
Regulatory Class: Class II
Product Code: OKP
Dated: July 22, 2016
Received: July 25, 2016

Dear Mr. Getlin:

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,

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: 2016.08.23 16:14:14 -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)*

Device Name
eNeura® sTMS Mini

Indications for Use *(Describe)*
The eNeura® sTMS mini is indicated for the acute treatment of pain associated with migraine headache with aura.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Notification (K161663)

GENERAL INFORMATION [807.92(a)(1)]

Applicant:
eNeura® Inc
715 North Pastoria Avenue
Sunnyvale, CA 94085
U.S.A.
Phone: 408-245-6400
FAX: 408-245-6424

Contact Person:
Larry W. Getlin
Regulatory Consultant for eNeura® Inc
2690 Pheasant Road
Orono, MN 55331
U.S.A.
E-mail: lwgetlin@gmail.com
Phone: 612-850-8144

Date Prepared: June 15, 2016

DEVICE INFORMATION [807.92(a)(2)]

Classification:
Class II

Product Code:
OKP

Trade Name:
sTMS mini

Generic/Common Name per 21 CFR§882.5808:
Transcranial magnetic stimulator for headache

PREDICATE DEVICE(S) [807.92(a)(3)]

SpringTMS® (K140094)

DEVICE DESCRIPTION [807.92(a)(4)]

The sTMS mini is a portable, hand-held device that delivers a brief single pulse of magnetic energy at 0.9 Tesla to the back of the head to induce an electrical current in a portion of the brain, called the occipital cortex, to stop or lessen the effects of migraine headaches. Since a single pulse of magnetic stimulation is emitted, this method of stimulation is called single pulse transcranial magnetic stimulation or sTMS. The sTMS mini is indicated for the acute treatment of pain associated with migraine headache with aura. The device is designed for patient use where treatments are self-administered and can be delivered in a variety of settings including the home or office. The device is intended for prescription use only.

INDICATIONS FOR USE [807.92(a)(5)]

The eNeura® sTMS mini is indicated for the acute treatment of pain associated with migraine headache with aura.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the sTMS mini are substantially equivalent to the predicate device, SpringTMS (K140094). Table 1 lists the technological characteristics of the sTMS mini and the predicate device and provides the rationale to support a determination of substantial equivalence. Any differences between the devices do not raise any new issues of safety or efficacy.

Table 1: Summary of Technological Characteristics

Feature	SpringTMS®	sTMS mini	Substantial Equivalence Rationale
510(k) Number	K140094	TBD	--
Operating Principle	• Induces electrical current in region near coil • Transcranial • Evoked response • Stimulation on the occipital cortex • Single Pulse TMS (sTMS)	• Induces electrical current in region near coil • Transcranial • Evoked response • Stimulation on the occipital cortex • Single Pulse TMS (sTMS)	N/A (same)
Design	• Time varying magnetic field • Non-invasive	• Time varying magnetic field • Non-invasive	N/A (same)

Table 1: Summary of Technological Characteristics (cont.)

Feature	SpringTMS®	sTMS mini	Substantial Equivalence Rationale
Use Authorization	The user must insert a SIM chip to use the device for a programmed duration. The programmed duration corresponds to the prescribed months of use. The SIM chip is only available under physician prescription.	The user must insert a SIM chip to use the device for a programmed duration. The programmed duration corresponds to the prescribed months of use. The SIM chip is only available under physician prescription.	N/A (same)
Display	LCD display	LED indicators	In both devices, the display serves to communicate device status to the patient and no additional risks or hazards have been identified related to this change.
Magnetic Field	0.9 Tesla Peak @ 180 µs (total magnetic energy 140J)	0.9 Tesla Peak @ 180 µs (total magnetic energy 140J)	N/A (same)
Current	4 mA/cm^2 induced at 1 cm	4 mA/cm^2 induced at 1 cm	N/A (same)
Electrical Power	Internally powered with rechargeable removable lithium ion battery pack. Battery pack charger mains input -- 100-240V AC, 50/60 Hz, output 12 V DC	Internally powered with rechargeable non-removable lithium ion battery pack. Battery pack charger mains input -- 100-240V AC, 50/60 Hz, output 12 V DC	The sTMS mini and predicate device utilize the same batteries, same voltage and power and both meet all criteria for establishing electrical safety.
Materials	Hand held portable stimulator in polycarbonate case (integral coil)	Hand held portable stimulator in polycarbonate case (integral coil)	N/A (same)
Where Used	Home-use and where the operator is	Home-use and where the operator is	N/A (same)
Dimensions and Weight	9 in. (23 cm) long 5 in. (13 cm) wide 3 in. (8 cm) deep 3.8 lb. (1.7 kg)	8.8 in. (22.4 cm) long 5.1 in. (13 cm) wide 2.7 in. (6.9 cm) deep 3.2 lb. (1.4 kg)	The reduced size of the sTMS mini raises no new issues of safety or efficacy.

SUBSTANTIAL EQUIVALENCE

The sTMS mini is substantially equivalent to the predicate device with regard to intended use or the indications for use and the fundamental scientific technology. Furthermore, the predicate SpringTMS and the proposed sTMS mini deliver the same energy in the same manner to the same area of the brain. Any differences between the two devices do not raise any new issues of safety or efficacy. Thus, the proposed sTMS mini is considered to be substantially equivalent to the predicate device.

PERFORMANCE DATA [807.92(b)]

All necessary performance testing was conducted on the proposed sTMS mini to support a determination of substantial equivalence to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing was conducted on the sTMS mini to support a determination of substantial equivalence to the predicate device. Table 2 lists the non-clinical performance testing conducted and the results supporting substantial equivalence.

Table 2: Non-Clinical Performance Testing and Substantial Equivalence Support

Testing Type	Test Description	Results Supporting Substantial Equivalence
Performance Bench Testing	Magnetic Pulse Characteristics vs. Time	Both devices have the same specification for magnetic pulse shape and both devices tested within specification. No new issues of safety or efficacy have been raised. The measured rate of change of the magnetic field is substantially equivalent.
	Magnetic Pulse Field Map	No new issues of safety or efficacy have been raised. The Magnetic Pulse Field Maps for the sTMS mini and the predicate device are substantially equivalent.
	Location of 5 Gauss Line	No new issues of safety or efficacy have been raised. The location of the 5 Gauss line for the sTMS mini and the predicate device are substantially equivalent.
Software Verification Validation Testing	sTMS mini Software Testing	The sTMS mini software was tested against requirements of the Software Requirements Specification (SRS) and no new issues of safety or efficacy have been raised. The sTMS mini software requirements specify device operations that result in the delivery of a magnetic pulse that is substantially equivalent to the magnetic pulse of the predicate device.
Electromagnetic Compatibility and Electrical Safety	Testing in accordance with the following standards: • IEC 60601-1-1 • IEC 60601-1-2	The sTMS mini and the predicate device met all acceptance criteria. No new issues of safety or efficacy have been raised. Therefore, the sTMS mini is substantially equivalent to the predicate.

The collective results of performance testing demonstrate that the materials chosen, the manufacturing processes, and design of the sTMS mini meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the sTMS mini does not raise new questions of safety or effectiveness when compared to the predicate device.

CONCLUSIONS [807.92(b)(3)]

The sTMS mini is considered by eNeura to be substantially equivalent to the predicate device.