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.
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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
510(k) Notification (K161663)

GENERAL INFORMATION [807.92(a)(1)]

Applicant:
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U.S.A.
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Contact Person:
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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)
**DETVICE 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.

**TECHNOCAL 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**

<table>
<thead>
<tr>
<th>Feature</th>
<th>SpringTMS®</th>
<th>sTMS mini</th>
<th>Substantial Equivalence Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Principle</td>
<td>510(k) Number</td>
<td>TBD</td>
<td>--</td>
</tr>
<tr>
<td></td>
<td>K140094</td>
<td>TBD</td>
<td></td>
</tr>
<tr>
<td>Induces electrical current in region near coil</td>
<td>· Induces electrical current in region near coil</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transcranial</td>
<td>· Transcranial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evoked response</td>
<td>· Evoked response</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stimulation on the occipital cortex</td>
<td>· Stimulation on the occipital cortex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single Pulse TMS (sTMS)</td>
<td>· Single Pulse TMS (sTMS)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Design</th>
<th>SpringTMS®</th>
<th>sTMS mini</th>
<th>Substantial Equivalence Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time varying magnetic field</td>
<td>· Time varying magnetic field</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-invasive</td>
<td>· Non-invasive</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CONFIDENTIAL
Table 1: Summary of Technological Characteristics (cont.)

<table>
<thead>
<tr>
<th>Feature</th>
<th>SpringTMS®</th>
<th>sTMS mini</th>
<th>Substantial Equivalence Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use Authorization</td>
<td>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.</td>
<td>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.</td>
<td>N/A (same)</td>
</tr>
<tr>
<td>Display</td>
<td>LCD display</td>
<td>LED indicators</td>
<td>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.</td>
</tr>
<tr>
<td>Magnetic Field</td>
<td>0.9 Tesla Peak @ 180 µs (total magnetic energy 140J)</td>
<td>0.9 Tesla Peak @ 180 µs (total magnetic energy 140J)</td>
<td>N/A (same)</td>
</tr>
<tr>
<td>Current</td>
<td>4 mA/cm² induced at 1 cm</td>
<td>4 mA/cm² induced at 1 cm</td>
<td>N/A (same)</td>
</tr>
<tr>
<td>Electrical Power</td>
<td>Internally powered with rechargeable removable lithium ion battery pack. Battery pack charger mains input -- 100-240V AC, 50/60 Hz, output 12 V DC</td>
<td>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</td>
<td>The sTMS mini and predicate device utilize the same batteries, same voltage and power and both meet all criteria for establishing electrical safety.</td>
</tr>
<tr>
<td>Materials</td>
<td>Hand held portable stimulator in polycarbonate case (integral coil)</td>
<td>Hand held portable stimulator in polycarbonate case (integral coil)</td>
<td>N/A (same)</td>
</tr>
<tr>
<td>Where Used</td>
<td>Home-use and where the operator is.</td>
<td>Home-use and where the operator is.</td>
<td>N/A (same)</td>
</tr>
<tr>
<td>Dimensions and Weight</td>
<td>9 in. (23 cm) long 5 in. (13 cm) wide 3.8 lb. (1.7 kg)</td>
<td>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)</td>
<td>The reduced size of the sTMS mini raises no new issues of safety or efficacy.</td>
</tr>
</tbody>
</table>

**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.
510(k) SUMMARY (CONT.)

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

<table>
<thead>
<tr>
<th>Testing Type</th>
<th>Test Description</th>
<th>Results Supporting Substantial Equivalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance Bench Testing</td>
<td>Magnetic Pulse Characteristics vs. Time</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Magnetic Pulse Field Map</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Location of 5 Gauss Line</td>
<td>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.</td>
</tr>
<tr>
<td>Software Verification Validation Testing</td>
<td>sTMS mini Software Testing</td>
<td>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.</td>
</tr>
<tr>
<td>Electromagnetic Compatibility and Electrical Safety</td>
<td>Testing in accordance with the following standards:</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>IEC 60601-1-1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>IEC 60601-1-2</td>
<td></td>
</tr>
</tbody>
</table>
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.