



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

February 25, 2019

Re: K182976  
Trade/Device Name: SpringTMS  
Regulation Number: 21 CFR 882.5808  
Regulation Name: Transcranial magnetic stimulator for headache  
Regulatory Class: Class II  
Product Code: OKP  
Dated: January 17, 2019  
Received: January 18, 2019

Dear Larry 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**John Marler -S** Digitally signed by John Marler -S  
Date: 2019.02.25 16:58:23 -05'00'

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

## Indications for Use

510(k) Number (if known)

K182976

Device Name

SpringTMS®

Indications for Use (Describe)

The eNeura Inc. SpringTMS® is indicated for the acute and prophylactic treatment of migraine headache in adolescents (age 12 and older) and adults.

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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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.\***

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## 510(k) Summary K182976

### GENERAL INFORMATION [807.92(a)(1)]

**Applicant:**

eNeura<sup>®</sup> 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<sup>®</sup> Inc.  
2690 Pheasant Road  
Orono, MN 55331  
USA  
Phone: 612-850-8144

**Date Prepared:**

October 24, 2018

### DEVICE INFORMATION [807.92(a)(2)]

**Trade Name:**

SpringTMS<sup>®</sup>

**Generic/Common Name:**

Transcranial magnetic stimulator for headache

**Classification:**

21 CFR§882.5808

**Product Code:**

OKP

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

The eNeura SpringTMS is substantially equivalent to the eNeura SpringTMS predicate device K162797. These products are technically identical. This traditional 510(k) is for a labeling expansion only.

### DEVICE DESCRIPTION [807.92(a)(4)]

The SpringTMS<sup>®</sup> is a portable, hand-held device that is designed and intended to deliver 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 SpringTMS is indicated for the acute and prophylactic treatment of migraine headache. 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.

The SpringTMS delivers the same energy and maintains the same operational characteristics as the SpringTMS device cleared in K162797. No changes in design or manufacturing process have been made that could affect device functionality. All functional aspects of the device remain the same as K162797, including the strength and nature of the magnetic field generated and the pulse generation.

**INTENDED USE/INDICATIONS FOR USE [807.92(a)(5)]**

The eNeura® Spring TMS® is designed and intended to deliver brief duration, pulsed, magnetic fields that are externally directed at spatially discrete regions of the brain to induce electric currents in the brain (Product Code OKP).

The eNeura Inc. SpringTMS® is indicated for the acute and prophylactic treatment of migraine headache in adolescents (age 12 and older) and adults.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]**

The eNeura SpringTMS is substantially equivalent to the previously cleared SpringTMS device (K162797). It has the same Intended Use (to deliver externally directed, pulsed, magnetic fields to induce electric currents in spatially discrete regions of the brains of patients with migraine headache). No changes in materials, design or manufacturing process have been made that could affect device functionality. All functional aspects of the device remain the same, as described in K162797, including the strength and nature of the magnetic field generated and the pulse generation. Thus, the technological characteristics remain the same as the predicate device.

**Table 1: Substantial Equivalence Table – Regulatory Information**

<b>Feature</b>	<b>Subject Device</b>	<b>Predicate Device</b>	<b>Analysis of Differences</b>
Device Name	SpringTMS	SpringTMS	Same
Manufacturer	eNeura Inc.	eNeura Inc.	Same
510(k) Number	Not Assigned	K162797	N/A
Regulation Number	21 CFR§882.5808	21 CFR§882.5808	Same
Class	Class II	Class II	Same
Classification	Transcranial magnetic stimulator for headache	Transcranial magnetic stimulator for headache	Same
Product Code	OKP	OKP	Same
Indications for Use	The eNeura Inc. SpringTMS® is indicated for the acute and prophylactic treatment of migraine headache in adolescents (age 12 and older) and adults.	The eNeura Inc. SpringTMS® is indicated for the acute and prophylactic treatment of migraine headache.	Expansion of indications for use does not raise new issues of safety and effectiveness. Support for expansion of intended use is provided in this submission.

**Table 1: Substantial Equivalence Table – Regulatory Information (Cont.)**

<b>Feature</b>	<b>Subject Device</b>	<b>Predicate Device</b>	<b>Analysis of Differences</b>
Intended Use	The eNeura® SpringTMS® is designed and intended to deliver brief duration, pulsed, magnetic fields that are externally directed at spatially discrete regions of the brain to induce electric currents in the brain.	The eNeura® SpringTMS® is designed and intended to deliver brief duration, pulsed, magnetic fields that are externally directed at spatially discrete regions of the brain to induce electric currents in the brain.	Same
Fundamental Scientific Technology	Portable, hand-held device that is designed and intended to deliver 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.	Portable, hand-held device that is designed and intended to deliver 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.	Same

**SUBSTANTIAL EQUIVALENCE**

The Intended Use/Indications for Use for the predicate device (K162797) is substantially equivalent to the proposed Intended Use/Indications for Use for the SpringTMS device. There are no differences in the technological characteristics between the devices so no new issues of safety or effectiveness are raised. Thus, the subject SpringTMS is substantially equivalent to the predicate SpringTMS device.

**PERFORMANCE DATA [807.92(b)]**

The SpringTMS device is the same as the predicate device and no technological changes have occurred. All previous performance testing continues to apply.

**Clinical Testing Summary [807.92(b)(2)]**

The SpringTMS device is the same as the predicate device and no technological changes have occurred. Thus, clinical testing was not conducted for this premarket notification, nor was required to support the safety and performance of the SpringTMS for the expanded Intended Use/Indications for Use population. Please refer to K162797 for further information regarding the prospective, single-arm, non-randomized Non-Significant Risk clinical study (ESPOUSE) conducted by eNeura using the SpringTMS device.

**CONCLUSIONS [807.92(b)(3)]**

The SpringTMS device is the same as the predicate device and no technological changes have occurred. There are no differences in the technological characteristics between the devices, therefore no new issues of safety or effectiveness are raised. Thus, the SpringTMS is substantially equivalent to the predicate device.

**SUMMARY**

The SpringTMS is substantially equivalent to the predicate device.