510(k) SUMMARY

MAY 2 1 2014

510(k) Notification K140094

GENERAL INFORMATION

Applicant:
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U.S.A.
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Contact Person:
Larry Getlin
Regulatory Consultant for eNeura Therapeutics, LLC
2690 Pheasant Road
Orono, MN 55331
U.S.A.
Phone: 612-850-8144

DEVICINFORMATION

Trade Name: SpringTMS®

Generic/Common Name:
Transcranial magnetic stimulator for the treatment of migraine headache
21 CFR§882.5808

Classification:
Class II

Product Code:
OKP

PREDICATE DEVICE(S)

eNeura Therapeutics® Cerena™ Transcranial Magnetic Stimulator (K130556)

INTENDED USE

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

PRODUCT DESCRIPTION

The SpringTMS® 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 SpringTMS 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.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the SpringTMS are substantially equivalent to the predicate device. Table 1 lists the technological characteristics of the SpringTMS and the predicate device and provides the rationale to support a determination of substantial equivalence. Any differences in the technological characteristics of the device do not affect the safety and effectiveness of the device.

Table 1: Summary of Technological Characteristics

Feature	SpringTMS®	Cerena™ Transcranial Magnetic Stimulator	Substantial Equivalence Rationale
510(k) Number	K140094	K130556	New 510(k) submission
Operating Principle	• Induces electrical current in region near coil • Transcranial • Evoked response • Stimulation on the occipital cortex	• Induces electrical current in region near coil • Transcranial • Evoked response • Stimulation on the occipital cortex	N/A (same)
Design	• Time varying magnetic field • Non-invasive	• Time varying magnetic field • Non-invasive	N/A (same)
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.	None	The addition of this Use Authorization feature does not affect the operating principle or performance of the device and no additional risks or hazards have been identified related to this change.
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 lithium ion battery pack. Battery pack charger mains input -- 100-240V AC, 47/63 Hz, output 12 V DC	Externally powered by AC/DC power adapter. Mains input -- 100-240V AC, 50/60 Hz, output 12 V DC	The SpringTMS and predicate device utilize the 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)	13 in. (33 cm) long 5 in. (13 cm) wide 5 in. (13 cm) deep 3.4 lb. (1.54 kg)	The form factor changes raise no new issues of safety or efficacy.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate device is identical to the proposed indications for use for the SpringTMS. The differences in the technological characteristics (Replacement of LED indicators with LCD screen, addition of the Use Authorization Feature, power supply type change and minor dimensional changes) do not raise any new issues of safety or effectiveness. Thus, the SpringTMS is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing was conducted on the SpringTMS 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 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 SpringTMS 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 SpringTMS and the predicate are substantially equivalent.

Software Verification Validation Testing	SpringTMS Software Testing	SpringTMS Software met all requirements of the SRS. No new issues of safety or efficacy have been raised. All safety and performance specifications for the SpringTMS SRS are substantially equivalent to those in the SRS for the predicate.
Electromagnetic Compatibility and Electrical Safety	Testing in accordance with the following standards: • IEC 60601-1:2005 • IEC 60601-1-2:2007	The SpringTMS and the predicate device met all acceptance criteria. No new issues of safety or efficacy have been raised. Therefore the SpringTMS is substantially equivalent to the predicate.

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

CONCLUSION

The SpringTMS is substantially equivalent to the predicate device. The indications for use is identical to that of the predicate device, and the product performance testing has demonstrated that the SpringTMS is as safe, as effective and performs in the same manner as the predicate device in terms of intended use, safety and technological characteristics, and patient populations. The differences include the device external design such as size and weight, display type, power supply type, and the authorization system for the device use; however, those changes do not raise any new safety or efficacy concerns. The information contained in this 510(k) premarket notification demonstrates the substantial equivalence of the SpringTMS to the predicate device.

SUMMARY

The SpringTMS is substantially equivalent to the predicate device.

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

May 21, 2014

eNeura Therapeutics, LLC
c/o Larry Getlin
2690 Pheasant Road
Orono, MN 55331

Re: K140094
Trade/Device Name: Spring TMS®
Regulation Number: 21 CFR §882.5808
Regulation Name: Transcranial magnetic stimulator for the treatment of migraine headache
Regulatory Class: Class II
Product Code: OKP
Dated: April 18, 2014
Received: April 21, 2014

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" (21CFR 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 yours,

Carlos L. Pena -S

Carlos L. Peña, Ph.D., M.S.
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)*
K140094

Device Name
eNeura Therapeutics Spring TMS

Indications for Use *(Describe)*
The eNeura Therapeutics® Spring TMS® 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)*

Carlos L. Pena -S

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:

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PRAStaff@fda.hhs.gov

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