May 16, 2023

eNeura, Inc.
℅ Larry Getlin
Regulatory Consultant
eNeura, Inc
2690 Pheasant Road
Orono, Minnesota 55331

Re: K230358
Trade/Device Name: SAVI Dual (TM) Migraine Therapy
Regulation Number: 21 CFR 882.5808
Regulation Name: Transcranial Magnetic Stimulator For Headache
Regulatory Class: Class II
Product Code: OKP
Dated: February 10, 2023
Received: February 10, 2023

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jitendra V. Virani -S

CDR Jitendra Virani
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230358

Device Name

SAVI Dual™ Migraine Therapy

Indications for Use *(Describe)*

The SAVI Dual™ Migraine Therapy device 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)*

XX 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.

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Date Prepared: 16-May-23

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Submission Correspondent: Larry W. Getlin

Proprietary or Trade Name: SAVI Dual Migraine Therapy

Regulation Code: 21 CFR§882.5808

Regulation Name(s): Transcranial Magnetic Stimulator for Headache

Device Class: Class II

Product Code: OKP

Predicate Device: K182976 – SpringTMS
Reference Device: K161663 – sTMS mini

Modification:
The subject device is similar to the predicate device except for:

- Hardware Modifications
- Software (firmware) updates

Device Description:
The SAVI Dual Migraine Therapy device 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 SAVI Dual is indicated for the acute and prophylactic treatment of migraine headache in adolescents (age 12 and older) and adults. 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. To use the device, the user must either insert a SIM chip to use the device for a programmed duration or the user may connect wirelessly via a cellular connection for the programmed duration. The programmed duration corresponds to the prescribed months of use.

Indications for Use:
The SAVI Dual™ Migraine Therapy is indicated for the acute and prophylactic treatment of migraine headache in adolescents (age 12 and older) and adults.

Table 5.1 – Comparison – Subject vs. Predicate and Reference Devices

Feature	SAVI Dual™ Migraine Therapy Device	SpringTMS® Predicate Device	sTMS mini Reference Device	Substantial Equivalence Rationale
Manufacturer	eNeura, Inc.	eNeura, Inc.	eNeura, Inc.	--
510(k) Number	New Submission	K182976	K161663	--
Indications for Use	The SAVI Dual™ Migraine Therapy device 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 in adolescents (age 12 and older) and adults.	The eNeura® sTMS mini is indicated for the acute treatment of pain associated with migraine headache with aura.	Indications for Use are identical to the predicate device.
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	• 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	• Time varying magnetic field • Non-invasive	N/A (same)
Use Authorization	With the SAVI Dual™ Migraine Therapy device, the user may connect either with the SIM chip just as the predicate or the user may connect wirelessly via a cellular connection for the programmed duration. The programmed duration corresponds to the prescribed months of use. The device remains 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.	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.	Subject device allows for a wireless connection / communication for user to use the device for the programmed duration in addition to the use of SIM chip. No new issues of safety or efficacy are raised with this change.
Display	LED indicators	LCD display	LED indicators	Subject device has the same display as the reference device. No new issues of safety or efficacy are raised with this change.

Feature	SAVI Dual™ Migraine Therapy Device	SpringTMS® Predicate Device	sTMS mini Reference Device	Substantial Equivalence Rationale
Magnetic Field	0.9 Tesla Peak @ 180 µs (total magnetic energy 140J)	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/cm2 induced at 1 cm	4 mA/cm2 induced at 1 cm	4 mA/cm2 induced at 1 cm	N/A (same)
Electrical Power	Internally powered with rechargeable embedded lithium ion battery pack. Battery pack charger mains input -100-240V AC, 50/60 Hz, output 12 V DC	Internally powered with rechargeable embedded lithium ion battery pack. Battery pack charger mains input -100-240V AC, 50/60 Hz, output 12 V DC	Internally powered with rechargeable embedded lithium ion battery pack. Battery pack charger mains input -100-240V AC, 50/60 Hz, output 12 V DC	N/A (same)
Materials	Hand held portable stimulator in polycarbonate case (integral coil)	Hand held portable stimulator in polycarbonate case (integral coil)	Hand held portable stimulator in polycarbonate case (integral coil)	N/A (same)
Environment of Use	Home-use and where the operator is	Home-use and where the operator is	Home-use and where the operator is	N/A (same)
Dimensions and Weight	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)	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)	Subject device is identical in size as the reference device (sTMS mini) No new issues of safety or efficacy are raised with this change.
Compliance to Standards	IEC 60601-1-2 IEC 60601-1 IEC 60601-1-11	IEC 60601-1-2 IEC 60601-1 IEC 60601-1-11	IEC 60601-1-2 IEC 60601-1 IEC 60601-1-11	N/A (same)

Substantial Equivalence Discussion

Intended Use/ Indications for Use
The indications for use are identical to those which were cleared for the predicate device, SpringTMS, under K182976.

Patient Population
The patient population is identical to that cleared for the predicate device, SpringTMS, under K182976.

Design and Technology
The SAVI Dual™ Migraine Therapy device, like the predicate device, 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 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.

To use the subject device, the user must either insert a SIM chip to use the device for a programmed duration or the user may connect wirelessly via a cellular connection for the programmed duration. The programmed duration corresponds to the prescribed months of use. The predicate device use authorization by the patient is done by inserting only a SIM chip into the device. Addition of the wireless cellular connection for subject device does not raise any new issues of safety or efficacy.

Thus, the design and technological characteristics of the SAVI Dual are substantially equivalent to the predicate device, SpringTMS (K182976).

Principles of Operation
The principle of operation remains unchanged to the predicate including that each device:

- Induces electrical current in region near coil
- Transcranial
- Evoked response
- Stimulation on the occipital cortex

Use Authorization:
With the SAVI Dual™ Migraine Therapy device, the user may connect either with the SIM chip just as the predicate or the user may connect wirelessly via a cellular connection for the programmed duration. The programmed duration corresponds to the prescribed months of use. The device remains under physician prescription only. Though the predicate device use authorization only allowed for use by the patient inserting a SIM chip into the device, this technology modification does not raise any new issues of safety or efficacy.

Environment of Use
The environment of use is identical to that cleared for the predicate device, SpringTMS under K182976.

Non-Clinical Testing

All necessary performance testing was conducted on the proposed SAVI Dual to support a determination of substantial equivalence to the predicate device. The testing performed is provided in the section below:

Table 5.2 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 subject device 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 subject device and the predicate device are substantially equivalent.
Software Verification Validation Testing	SAVI Dual Software Testing	The SAVI Dual software was tested against requirements of the Software Requirements Specification (SRS) and no new issues of safety or efficacy have been raised. The 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 • IEC 60601-1-11	The subject device met all acceptance criteria. No new issues of safety or efficacy have been raised. Therefore, the SAVI Dual is substantially equivalent to the predicate.

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

Substantial Equivalence Conclusion

The SAVI Dual is considered by eNeura to be substantially equivalent to the predicate device. Any differences do not present different questions of safety or effectiveness than the predicate device.