August 13, 2021

Soterix Medical, Inc.
Abhishek Datta, Ph.D.
Chief Technology Officer
237 West 35 Street, #1401
New York, New York 10001

Re: K192823
Trade/Device Name: MEGA-TMS
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF
Dated: July 14, 2021
Received: July 14, 2021

Dear Dr. Abhishek Datta:

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,

Xiaolin Zheng, Ph.D.
Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic 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)*
K192823

Device Name
MEGA-TMS

Indications for Use *(Describe)*
Stimulation of peripheral nerves for diagnostic purposes.

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.

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510(K) SUMMARY

Date Prepared:	August 26, 2019
Submitter Information:	
Company Name:	Soterix Medical, Inc.
Company Address:	237 W 35th Street Suite 1401 New York, NY 10001
Contact Person:	Abhishek Datta Phone: 888-990-8327 Fax: 212-315-3232
Device Information:	
Trade Name:	MEGA-TMS
Common Name:	MEGA-TMS
Classification Name:	GWF - Evoked Response Electrical Stimulator (21 CFR 882.1870)
Device Class:	Class II
Predicate Devices:	Magstim 200^2 with Double 70mm Remote Coil (K060847) Magstim Company US, LLC. (Primary Predicate) Class II MagPro R30 incl. MagOption, X100, X100 incl. MagOption (K091940) Tonica Elektronik A/S (Secondary Predicate) Class II
Device Description:	The MEGA-TMS is intended for stimulation of peripheral nerves for diagnostic purposes.

The device introduces electrical stimulation to tissue through magnetic induction generated from the coil. The obtained responses of stimulated structures is recorded with an EMG system for further diagnostic evaluation. The MEGA-TMS device is intended to be paired with a Focus EMG device cleared under FDA 510(k): K102610.

Magnetic stimulation is used for peripheral nerve conduction studies and to evaluate peripheral nervous system.

Indications for Use:

Stimulation of peripheral nerves for diagnostic purposes.

Comparison of Technological Characteristics with the Predicate Devices:

At a high level, the subject and predicate devices (K060847 and K091940) are based on the following technological elements:

- Introduction of electrical stimulation through tissue, through magnetic induction generated from coils
- Induced electrical current in nearby tissue causing nerve impulse
- Stimulus intensity control, core material and coil positioning

The following technical differences exist between the subject device and predicate devices:

- Smaller pulse width
- Change in maximum repetition rate
- Coil temperature/intensity indicators for stimulation graphical user interface
- Maximum voltage generated
- Peak magnetic field generated

Parameter	MEGA-TMS Proposed	Magstim 200^2 with Double 70mm Remote Coil (Primary Predicate)	MagPro R30 incl. MagOption, X100, X100 incl. MagOption (Secondary Predicate)	Comparison
510(k)	K192823	K060847	K091940	-

Parameter	MEGA-TMS Proposed	Magstim 200^2 with Double 70mm Remote Coil (Primary Predicate)	MagPro R30 incl. MagOption, X100, X100 incl. MagOption (Secondary Predicate)	Comparison
Device Name and Model	MEGA-TMS	Magstim 200^2	MagPro X100, MagPro X100 with MagOption MagPro R30 with MagOption	-
Manufacturer	Neurosoft Ltd.	Magstim Company US, Llc.	Tonica Elektronik A/S	-
Indications For Use	Stimulation of peripheral nerves for diagnostic purposes.	Stimulation of peripheral nerves for diagnostic purposes.	The magnetic stimulators are intended to be used for stimulation of peripheral nerves for diagnostic purposes.	**Identical**
Contraindications For Use	MEGA-TMS/Neuro-MS and its accessories should not be used on or in the vicinity of patients or users with cardiac demand pacemakers, implanted electronic devices, cochlear implants, pregnant women.	Magstim 200^2 and its accessories should not be used on or in the vicinity of patients or users with cardiac demand pacemakers, implanted defibrillators and/or implanted neurostimulators.	Do not use the equipment on patients with cardiac pacemakers, cochlear implants or other implanted electronic devices. Do not apply the magnetic stimuli to the head, neck or abdomen of pregnant women.	MEGA-TMS includes additional contraindications to the ones mentioned in the Primary Predicate. MEGA-TMS contraindications are identical to the Secondary Predicate.

Parameter	MEGA-TMS Neurosoft, Ltd. Proposed	Magstim 200^2 with Double 70mm Remote Coil Magstim Company, Llc. (Primary Predicate)	MagPro R30 incl. MagOption, X100, X100 incl. MagOption (Secondary Predicate)	Comparison
Maximum Voltage	2.8 kV	2.8 kV	1.8 kV	MagPro has a smaller range of maximum voltage.
Maximum Repetition Rate	30% - 0.7 sec / 1.42 Hz 50% - 1 sec / 1 Hz 100%- 3.3 sec / 0.3 Hz	30% - 2 sec / 0.5 Hz 50% - 3 sec / 0.33 Hz 100%- 4 sec /0.25 Hz	30% - 0.05 sec / 20 Hz 45% - 0.1 sec / 10 Hz 100%- 0.5 sec / 2 Hz	Differences in maximum repetition rate
Pulse Width	80+/-15 µsec (monophasic) 120 +/- 15 µsec (power)	100 µsec (monophasic)	70 µsec (monophasic) 100 µsec (power monophasic)	MEGA-TMS has a slightly lower pulse width in the monophasic mode in comparison to the primary predicate. MEGA-TMS has a slightly higher pulse width in the monophasic mode in comparison to the secondary predicate.

Parameter	MEGA-TMS Neurosoft, Ltd. Proposed	Magstim 200^2 with Double 70mm Remote Coil Magstim Company, Llc. (Primary Predicate)	MagPro R30 incl. MagOption, X100, X100 incl. MagOption (Secondary Predicate)	Comparison
Stimulus Intensity	0-100% Adjustable	0-100% Adjustable	0-100% Adjustable	**Identical**
Coil Positioning	Periphery other than brain	Periphery other than brain	Periphery other than brain	**Identical**
Core Material	Air Core	Air Core	Air Core	**Identical**
Peak Magnetic Field	2.5 T	2.1 T	N/A	MEGA-TMS has a slightly larger peak magnetic field than
Certificates: IEC 60601-1	YES	YES	YES	**Identical**
Dimensions (in.) [L x W x H]	20.87'' x 19.69'' x 7.09''	18.11'' x 14.76'' x 6.30''	MagPro: 210 x 530 x 400mm MagOption: 130 x 530 x 400mm	MEGA-TMS has a slightly larger stimulator unit.

Parameter	MEGA-TMS Neurosoft, Ltd. Proposed	Magstim 200^2 with Double 70mm Remote Coil Magstim Company, Llc. (Primary Predicate)	MagPro R30 incl. MagOption, X100, X100 incl. MagOption (Secondary Predicate)	Comparison
Weight (lbs., oz.) [without battery or electrode cables]	~66 lbs	~50 lbs	MagPro X100: 35kg / 77lbs MagOption: 25kg / 55lbs	MEGA-TMS has a slightly larger stimulator unit.
Menu Display	Coil Temperature and Intensity Indicators: Coil Type Coil State Armed/Disarmed State Power Charging/Discharging Status High Voltage Replace Coil	Coil Temperature and Intensity Indicators: Coil State Armed/Disarmed State Power Status Default Condition Replace Coil	MagPro X100 has 1 display. All parameter settings can be shown on the display. · Intensity · Repetition rate · Pulses in train · Number of trains · Inter train interval · Start delay · Amplitude · Realized di/dt Status: enable/disable · Coil temperature · Coil type · Available stimuli · Event log information and date/time · Treatment sequence can be stored and reused. Event log and Amplitude log can be exported. · Continuously readout of di/dt controlling the stability of the produced magnetic stimulation	MEGA-TMS has a slightly more indicators shown in the menu display compared to the predicate device.

Performance Testing:

The following performance data were provided in support of the substantial equivalence determination.

Safety and EMC

Electrical and mechanical safety and electromagnetic compatibility testing were conducted to demonstrate that the MEGA-TMS device is compliant with IEC 60601-1 (Edition 3.1) and IEC 60601-1-2 (Edition 4).

Design

Design verification demonstrated that the device functions as intended. Design validation was demonstrated using software validation testing and literature review. Validation testing confirmed that the device met end-user needs, intended use and evidence of device operation in actual use conditions.

Software

Following FDA's Guidance for Industry and Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," software verification and validation was conducted.

Risk Management

The potential risks of MEGA-TMS were identified and evaluated in compliance with ISO 14971. All risks were determined to be appropriately mitigated with risk control measures to acceptable residual levels.

Electric and Magnetic Field Characteristics

For electric field, actual measurements were recorded and simulations performed. For magnetic field, pulse shape information, magnetic field spatial distribution, magnetic field strength gradient, linearity, and reliability information were collected. Bench top measurements of field strength were taken at coil surface and 20 mm above to determine spatial distribution of magnetic field.

Conclusion:

The non-clinical data demonstrates that the differences in technological characteristics between the subject device and predicate devices do not raise new or different questions of safety and effectiveness and is therefore comparable to the predicate devices that are currently marketed for the same intended use.