April 6, 2020

Soterix Medical, Inc.
Abhishek Datta
Chief Technology Officer
237 W 35 St, 1401
New York, New York 10001

Re: K191422
Trade/Device Name: Neural Navigator
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW
Dated: January 6, 2020
Received: January 7, 2020

Dear 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,

Pamela Scott
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191422

Device Name
The Neural Navigator

Indications for Use *(Describe)*
The Neural Navigator is a neuronavigation system indicated for accurate positioning of the treatment coil of the CloudTMS Therapy System with respect to target brain regions based on data obtained from MRI measurements. Specifically, the Neural Navigator is indicated for use with the following CloudTMS Therapy System coils manufactured by Neurosoft Ltd: AFEC-02-100 and AFEC-02-100-C.

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

Submission Date: 01/06/20

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: *The Neural Navigator*

Common Name: Neural Navigator

Classification Name: HAW - Stereotaxic Instrument (21 CFR 882.4560)

Device Class: Class II

Predicate Devices:

1. Nexstim Navigated Brain Therapy (NBT) System 2 (K171902)
   Nexstim Plc
   Class II (Primary Predicate)

2. Nexstim Navigated Brain Stimulation (NBS) System 4 (K112881)
   Nexstim Oy
   Class II (Reference Device)

Device Description:

The Neural Navigator combines MRI-based, 3-D localization of cortical motor areas of the brain with non-invasive TMS and simultaneous EMG measurement to locate areas of the brain that are capable of evoking muscle responses when stimulated, and to locate the target area for depression therapy. The Neural Navigator software is used to import a patient's MR image slices through standard DICOM communication protocols, and automatically generates an accurate 3-D model of the patient's head, and a custom automatic tissue segmentation routine to reveal anatomical structures of the brain surface in 3D.

Intended Use/Indications:

The Neural Navigator is a neuronavigation system indicated for accurate positioning of the treatment coil of the CloudTMS Therapy System with respect to target brain regions based on data obtained from MRI measurements. Specifically, the Neural Navigator is indicated for use with the following CloudTMS Therapy System coils manufactured by Neurosoft Ltd: AFEC-02-100 and AFEC-02-100-C.

SOTERIX MEDICAL, INC.
510(k) Application Neural Navigator

Technological Comparison: The Neural Navigator uses the same technological principle as the predicate devices to accomplish its intended use, namely the accurate positioning of a TMS or rTMS coil with respect to target brain regions. In conjunction with a rTMS device approved for the treatment of major depressive disorder, the Neural Navigator's intended use is similar to that of the primary predicate, that also combines a TMS device and MRI guidance of coil placement. A full comparison of technological characteristics is provided in the table below.

Parameter	Neural Navigator	NBT System 2 (Primary Predicate)	NBS System 4 (Reference Predicate)
510(k)	Proposed Device	K171902	K112881
Device Name and Model	Neural Navigator	NBT System 2	NBS System 4
Manufacturer	Brain Science Tools BV	Nexstim Plc	Nexstim Oy
Indications For Use	The Neural Navigator is a neuronavigation system indicated for accurate positioning of the treatment coil of the CloudTMS Therapy System with respect to target brain regions based on data obtained from MRI measurements. Specifically, the Neural Navigator is indicated for use with the following CloudTMS Therapy System coils manufactured by Neurosoft Ltd: AFEC-02-100 and AFEC-02-100-C.	The NBT System 2 is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.	The NBS System 4 is indicated for the non-invasive mapping of the primary motor cortex of the brain to its cortical gyrus. The NBS System 4 provides information that may be used in the assessment of the primary motor cortex for pre- procedural planning.

Parameter	Neural Navigator	NBT System 2 (Primary Predicate)	NBS System 4
Device Description	The Neural Navigator combines MRI-based, 3-D localization of cortical motor areas of the brain with non-invasive TMS and simultaneous EMG measurement to locate areas of the brain that are capable of evoking muscle responses when stimulated, and to locate the target area for depression therapy. The Neural Navigator software is used to import a patient's MR image slices through standard DICOM communication protocols, and automatically generates an accurate 3-D model of the patient's head and a custom automatic tissue segmentation routine to reveal anatomical structures of the brain surface in 3D.	The Nexstim NBT System 2 combines MRI-based, 3-D localization of cortical motor areas of the brain with non-invasive TMS and simultaneous EMG measurement to locate areas of the brain that are capable of evoking muscle responses when stimulated, and to locate the target area for depression therapy. The Nexstim NBT System 2 software is used to import a model of the patient's MR image slices through standard DICOM communication protocols, and generates an accurate 3-D model of the patient's head which can be "peeled back" to reveal the anatomical structures of the brain.	The NBS System 4 combines MRI based, 3D localization of cortical motor areas of the brain with non-invasive TMS and simultaneous EMG measurement to locate areas of the brain that are capable of evoking muscle responses when stimulated. The NEXSPEECH is intended to be used in conjunction with the NBS System 4 for localization and assessment of cortical areas of speech function for pre-procedural planning.

Parameter	Neural Navigator	NBT System 2 (Primary Predicate)	NBS System 4 (Reference Predicate)
Compatible Coils	• Neurosoft AFEC-02-100-C Coil • Neurosoft AFEC-02-100 Coil	• Nexstim Focal Coil • Nexstim Cooled Coil	• Nexstim Focal Coil • Nexstim High Intensity Coil • Nexstim Cooled Coil
Regulatory Class	Class II	Class II	Class II
Product Code	HAW	HAW, OBP, GWF, IKN	HAW, GWF, IKN
Tracking System Accuracy	1.4 mm RMS, 0.5 degrees RMS (accuracy of localization of tool)	1.6 mm (mean error in localization of the tool)	1.6 mm (mean error in localization of the tool)
System Accuracy	3mm +/- 2.1 mm (when navigating with hand-held probe), 5mm +/- 2.1 mm (when navigating with TMS coil)	5.73 mm (mean) 11.46 mm (95% CI)	5.73 mm (mean) 11.46 mm (95% CI)

Parameter	Neural Navigator	NBT System 2 (Primary Predicate)	NBS System 4 (Reference Predicate)
Navigation Principle	Based on Anatomy (MRI picture) and calibrated electric field maximum	Based on Anatomy (MRI picture) and calculated electric field	Based on Anatomy (MRI picture) and calculated electric field
Operating Conditions	5°C - 40°C; between 10%-90% non-condensing humidity. Max allowed height for usage is 2000 m above sea level. Air pressure 79 kPa-106 kPa	15°C- 30°C; between 30%-75% non-condensing humidity. Air Pressure 80 kPa-106 kPa	15°C- 30°C; between 30%-75% non-condensing humidity. Air Pressure 80 kPa-106 kPa
Intended Users	Trained Clinical professionals	Trained Clinical professionals	Trained Clinical professionals
Electrical Rating	100-240 VAC, 50/60 Hz	120-240 VAC, 50/60 Hz	120-240 VAC, 50/60 Hz
Dimensions (Electronics Unit)	18.5 cm x 29.2 cm x 6.4 cm	27.3 cm x 6.9 cm x 6.9 cm (tracking unit)	27.3 cm x 6.9 cm x 6.9 cm (tracking unit)
Power Consumption	50 VA	1000 VA	1000 VA
Position Tracker Model Name	BrainTRAK	Polaris Tracking System	Polaris Tracking System
Prescription Use	Yes	Yes	Yes
Imaging Modalities	MR Based	MR Based	MR Based

Parameter	Neural Navigator	NBT System 2 (Primary Predicate)	NBS System 4 (Reference Predicate)
MR image loading in DICOM, Nifti, and Analyze	Yes	Yes	Yes
Selection of Targets via Anatomical and Functional Landmarks	Yes	Yes	Yes
DICOM Conformance	DICOM conformance statement available.	DICOM conformance statement available.	DICOM conformance statement available.
Planning Features	Stimulation targets to deliver TMS to specific area; includes visibility, location and description of the target.	Stimulation targets to deliver TMS to specific area; includes visibility, location and description of the target.	Stimulation targets to deliver TMS to specific area; includes visibility, location and description of the target.
2D Viewing	Yes: axial, coronal, siggatal slices through configurable cut planes in 3D scene	Yes	Yes
3D Viewing	Yes: 3D viewing of skin, brain surface and activation maps, using surface rendering techniques	Yes	Yes
Electrical Safety	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6
ISO Standards Met	ISO 13485, IEC 62304, IEC 62366, IEC 14971, IEC 80002-1, ISO 15223-1	ISO 13485, IEC 62304, IEC 62366, ISO 14971, ISO 10993-1,	ISO 13485, IEC 62304, IEC 62366, ISO 14971 ISO 10993-1,

Parameter	Neural Navigator	NBT System 2 (Primary Predicate)	NBS System 4 (Reference Predicate)
Scanner Interface	DICOM import of MR images; load fMRI/PET images through import wizard. Full dicom conformance statement avialable. Mapping results exported as XML text file.	Mapping results exported as DICOM images with voxel coloring according to motor response amplitudes. Screen captures of 3D mapping views stored as DICOM images.	DICOM import of MR images; load fMRI/PET images through import tab.
Registration Features	Cross-hairs to register specific MRI landmarks, digitization pen and head tracker sensors; registration integrity test to determine inaccuracies.	Cross-hairs to register specific MRI landmarks, digitization pen and head tracker LED indicators; may perform advanced registration digitizing nine scalp points; registration integrity test to determine inaccuracies.	Cross-hairs to register specific MRI landmarks, digitization pen and head tracker LED indicators; may perform advanced registration digitizing nine scalp points; registration integrity test to determine inaccuracies.

Basis for Equivalence:

Performance Testing: Bench and clinical testing demonstrated that the performance parameters of the Neural Navigator device are substantially equivalent to those of the predicate devices. A summary of the performance testing is provided in the table below.

Test	Test Method Summary	Results
Navigation Principle (Based on Anatomy and calibrated EF maximum)	Main navigation principle is 'point based registration' between MRI space and patient space, and the calibration of navigation tools. It is tested via: 1) Monte Carlo simulations of the mapping algorithm and the ensuing navigation are run 10,000 times using realistic position measurement noise conditions. 2) Clinical study using the CloudTMS coil (MEP mapping in 10 healthy volunteers). Both studies compared the targeted site with ground-truth	Tests confirm navigation based on MRI and navigation based on EF maximum. The navigation principle of predicate devices is also based on anatomy and calibrated EF

		maximum.
Coil Compatibility - Verification	1) Clamp tightly wraps around TMS coil handle. 2) Clamp tightly holds sensor in a socket. Coil clamp socket dimensions should be within 0.1 mm tolerance of required dimensions. 3) Material composition is Polyoxymethylene (POM)	Material Specs match Dimensions match (with 0.1 mm). Holding of the sensor at a fixed location with respect to TMS coil allows proper tracking of coil position and orientation. The predicate devices are similarly compatible to Nexstim branded coils
Coil Compatibility - Validation	Clinical Study using the CloudTMS coil (MEP mapping in 10 healthy volunteers)	The predicate devices are similarly compatible to Nexstim branded coils
Tracking System Accuracy	Static accuracy better than or equal to 1.4 mm as evidenced by test report provided by NDI (tracking system manufacturer) for every shipment (100% incoming inspection)	Test report confirmation. The tracking system accuracy of the predicate devices are 1.6 mm.
System Accuracy	1) Monte Carlo simulations of the mapping algorithm and the ensuing navigation are run 10,000 times using realistic position measurement noise conditions. 2) Clinical Study using CloudTMS coil (MEP mapping in 10 healthy volunteers)	1) Simulations confirm navigation accuracy of 4.55 mm with 4 markers. With 6 markers, accuracy drops to below 3.5 mm 2) accuracy of 4.74 mm for both coil orientations observed. The system accuracy of the predicate devices are 5.73mm
Product Safety Standards	Subject device was tested to the following standards: IEC 60601-1,IEC 60601-1-2,IEC 60601-1-6,IEC 80002-1,IEC 62366,IEC 62304,ISO 14971	Compliant Test Reports. The predicate device is compliant to the same safety standards
Imaging Modality	System Testing (testing of integrated product in a setting normally encountered by the intended user) and Clinical Study using CloudTMS coil (MEP mapping in 10 healthy volunteers)	The imaging modality is also MR based in predicate devices
Selection of targets via anatomical and functional landmarks	System Testing and Clinical Study	The same is also used in predicate devices

Labeling: The labeling of the Neural Navigator device is substantially equivalent to that of the predicate devices.

Conclusions from testing: The Neural Navigator device is substantially equivalent to the predicate devices. The Neural Navigator device is similar in intended use to the MRI guided coil placement component of its predicate device. Bench and clinical testing supports the conclusion that the performance parameters of the Neural Navigator device is substantially equivalent to the predicate devices, and any differences between the devices do not pose new questions of safety and effectiveness.