June 8, 2023

Neuronetics
Amanda Pentecost, PhD
Sr. Regulatory Affairs Specialist
3222 Phoenixville Pike
Malvern, Pennsylvania 19355

Re: K231350
Trade/Device Name: OCD MT Cap (85-00397-000)
Regulation Number: 21 CFR 882.5802
Regulation Name: Transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions
Regulatory Class: Class II
Product Code: QCI
Dated: May 1, 2023
Received: May 9, 2023

Dear Dr. Pentecost:

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,

Robert Kang -S

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231350

Device Name
OCD MT Cap (85-00397-000)

Indications for Use *(Describe)*
The NeuroStar Advanced Therapy system is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

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.

510(k) Summary

Date Prepared: June 7, 2023

Applicant:
Neuronetics, Inc.
3222 Phoenixville Pike
Malvern, PA 19355

Contact Person:
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Device Trade Name:
NeuroStar
NeuroStar TMS Therapy System
NeuroStar Advanced Therapy System
NeuroStar Advanced Therapy System for Mental Health

Device Common Name: Transcranial Magnetic Stimulator

Classifications: 21 CFR 882.5802

Product Codes: QCI

Predicate Device: NeuroStar Advanced Therapy System (K212289, K230029)
(Product Code: QCI)

Device Description / Technological Characteristics:

The NeuroStar Advanced Therapy System is a transcranial magnetic stimulation device. Specifically, it is a computerized, electromechanical medical device that produces and delivers non-invasive magnetic fields to induce electrical currents targeting specific regions of the cerebral cortex. Transcranial magnetic stimulation (TMS) is a non-invasive technique used to apply brief magnetic pulses to the brain. The pulses are administered by passing high currents through an electromagnetic coil placed adjacent to a patient's scalp. The pulses induce an electric field in the underlying brain tissue. When the induced field is above a certain threshold and is directed in an appropriate orientation relative the brain's neuronal pathway, localized axonal depolarizations are produced, thus activating neurons in the targeted brain region.

The NeuroStar Advanced Therapy System is an integrated system consisting of a combination of the following components:

- Mobile Console
- System Software
- Treatment Chair
- Ferromagnetic Treatment Coil
- Head Support System
- SenStar® Connect Treatment Link & SenStar® Treatment Link
- Treatment Pack (for use with the SenStar® Connect Treatment Link)
- MT Cap
- TrakStar™ Patient Data Management System
- D-Tect™ MT Accessory
- Beam F3 Treatment Pack
- OCD MT Cap

Proposed Change:

The only proposed change to the NeuroStar Advanced Therapy System is the addition the OCD MT Cap, a single-use wearable device that is intended to be used as an optional aid during the OCD Motor Threshold (MT) determination process. It is only worn by the patient during the MT determination process as a guide to facilitate determination of the patient's unique MT location. The OCD MT Cap outer surface contains a symmetrical gridlines that are centered on the back of the head and stem from a single point. These gridlines enable the clinician to easily move the coil incrementally without the need for manually moving the Anterior/Posterior (A/P) and Superior Oblique Angle (SOA) indicators to incrementally move the Treatment Coil between MT pulses. As the MT pulses are delivered to the patient during this process, the clinician monitors the patient for involuntary movement in the foot/feet in exactly the same manner as the current method.

There are no changes to the NeuroStar Advanced Therapy System nor to any other accessory to the system.

Indications for Use:

The NeuroStar Advanced Therapy System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

Performance Standards:

The OCD MT Cap has been tested and conforms to the following recognized consensus standards:

- ISO 10993-1

Non-clinical Testing:

The contents of this 510(k) comply with the FDA Guidance Document: "Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems - Guidance for Industry and Food and Drug Administration Staff."

A biocompatibility risk assessment was performed in accordance with ISO 10993-1 and the FDA Guidance Documents "Use of International Standard ISO 10993-1 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process' and revealed no biocompatibility concerns.

Additionally, usability testing was completed in accordance with FDA Guidance Document: "Applying Human Factors and Usability Engineering to Medical Devices," using IEC 62366-1 as a guide.

To summarize, the results of verification and validation testing confirmed that the OCD MT Cap can be successfully used to aid clinicians in the MT determination process to determine the patient's unique MT location.

Clinical Testing:

There is no clinical testing required to support this submission.

Conclusion:

The NeuroStar Advanced Therapy System and the predicate device have the same intended uses and technological characteristics. The use of the optional OCD MT Cap accessory does not raise any different questions regarding safety or effectiveness.

Technological Comparison

	NeuroStar Advanced Therapy System (Subject Device)	NeuroStar Advanced Therapy System (Predicate Device – K212289, K230029)	Explanation of Differences
Indications for Use	The NeuroStar Advanced Therapy System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD)	The NeuroStar Advanced Therapy System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD)	No Difference
Intended Use	Obsessive Compulsive Disorder	Obsessive Compulsive Disorder	No Difference
Anatomical Sites	Bilateral dorsomedial prefrontal cortex	Bilateral dorsomedial prefrontal cortex	No Difference
Target Population	Adult patients (ages 22-70) with Obsessive-Compulsive Disorder	Adult patients (ages 22-70) with Obsessive-Compulsive Disorder	No Difference
Clinical Setting	Inpatient and outpatient settings including physician's offices and clinics, hospitals, and general medical/surgical hospitals.	Inpatient and outpatient settings including physician's offices and clinics, hospitals, and general medical/surgical hospitals.	No Difference
Materials	Standard materials commonly used in the manufacture of electrical medical devices	Standard materials commonly used in the manufacture of electrical medical devices	No Difference
Biocompatibility	Patient-contacting device components use standard materials compliant with ISO 10993-1 that are commonly used in consumer products and medical device applications	Patient-contacting device components use standard materials compliant with ISO 10993-1 that are commonly used in consumer products and medical device applications	No Difference
Energy Source	Power console with magnetic coil for delivery for magnetic energy	Power console with magnetic coil for delivery for magnetic energy	No Difference
Electrical Safety & EMC	IEC 60601-1 compliant IEC 60601-1-2 compliant	IEC 60601-1 compliant IEC 60601-1-2 compliant	No Difference
Communication with TrakStar	Wireless (Wi-fi) and Ethernet cable	Wireless (Wi-fi) and Ethernet cable	No Difference
Sterility	No parts of the device, accessories or components are required to be sterilized	No parts of the device, accessories or components are required to be sterilized	No Difference
Coil Type	Ferromagnetic Iron core	Ferromagnetic Iron core	No Difference

	Internal cooling fan	Internal cooling fan	
Coil Positioning System	Integrated into Head Support System Laser-aided coil placement	Integrated into Head Support System Laser-aided coil placement	No Difference
Treatment Schedule	Weeks 1-5: 1 treatment session per day for 5 days Week 6: 1 treatment session per day for 4 days Total of 29 treatment sessions	Weeks 1-5: 1 treatment session per day for 5 days Week 6: 1 treatment session per day for 4 days Total of 29 treatment sessions	No Difference
Device Components	• Mobile Console • Ferromagnetic Coil for delivering treatment • Head Support System for coil positioning • MT Cap for coil positioning* • D-Tect™ MT Accessory for MT location and level determination* • Multi-use disposable for contact sensing and magnetic field quality control • Single-use treatment pack including disposable hygienic barriers and coil positioning head strap for use with the standard 5 cm method • Single-use treatment pack including disposable hygienic barriers and head strap for use with the Beam F3 method for determining treatment location and coil positioning* • OCD MT Cap for Coil positioning • TrakStar System for recording patient data	• Mobile Console • Ferromagnetic Coil for delivering treatment • Head Support System for coil positioning • MT Cap for coil positioning* • D-Tect™ MT Accessory for MT location and level determination* • Multi-use disposable for contact sensing and magnetic field quality control • Single-use treatment pack including disposable hygienic barriers and coil positioning head strap for use with the standard 5 cm method • Single-use treatment pack including disposable hygienic barriers and head strap for use with the Beam F3 method for determining treatment location and coil positioning* • TrakStar System for recording patient data	Different The addition of the OCD MT Cap is the subject of this 510(k). *Note: The MT Cap, D-Tect™ MT Accessory, and Beam F3 Treatment Pack are not intended to be used as part of the OCD treatment protocol.
%MT Range	25% to 140% MT	25% to 140% MT	No Difference
Pulses per Second (PPS) Range	For treatment: 1 to 30 PPS For MT determination: 0.1-0.3 PPS	For treatment: 1 to 30 PPS For MT determination: 0.1-0.3 PPS	No Difference
Induced Electrical field at 2 cm at 1.0 SMT	135 V/m (Nominal)	135 V/m (Nominal)	No Difference

Pulse Type	Biphasic Sinusoid	Biphasic Sinusoid	No Difference
Pulse Width	185 µS (Nominal)	185 µS (Nominal)	No Difference
Treatment Protocols	**Level:** 100% foot motor threshold level **Repetition Rate:** 20 PPS **Stimulation Time:** 2 s **Inter-train Interval:** 20 s **Session Duration:** As low as 18.3 min **Pulses per Session:** 2000 **Sessions Per Week:** 5 for Weeks 1-5 and 4 for Week 6	**Level:** 100% foot motor threshold level **Repetition Rate:** 20 PPS **Stimulation Time:** 2 s **Inter-train Interval:** 20 s **Session Duration:** As low as 18.3 min **Pulses per Session:** 2000 **Sessions Per Week:** 5 for Weeks 1-5 and 4 for Week 6	No Difference
Treatment Level Range	0.22 to 2.08 SMT Calibrated linear output	0.22 to 2.08 SMT Calibrated linear output	No Difference
Stimulation Time Pulse Train Duration Range	1 PPS: 1 to 600 s > 1 PPS: 1 to 20 s	1 PPS: 1 to 600 s > 1 PPS: 1 to 20 s	No Difference
Inter-train Interval Range	1 PPS: 0 to 600 s >1 PPS: 10 to 60 s	1 PPS: 0 to 600 s >1 PPS: 10 to 60 s	No Difference
Pulse per Treatment Session	Nominal: 2000 Maximum: 5000	Nominal: 2000 Maximum: 5000	No Difference