May 6, 2022

Neuronetics, Inc
Robin Fatzinger
Sr. Director, Regulatory Affairs
3222 Phoenixville Pike
Malvern, Pennsylvania 19355

Re: K212289
Trade/Device Name: NeuroStar Advanced Therapy for adjunctive treatment of OCD, NeuroStar Advanced Therapy System, NeuroStar TMS Therapy System, NeuroStar Advanced Therapy for Mental Health
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: April 6, 2022
Received: April 7, 2022

Dear Robin Fatzinger:

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 D. 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)*
K212289

Device Name
NeuroStar Advanced Therapy System

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.

510k Summary

510(k) Number:	K212289
Date Prepared:	06 May 2022
Applicant:	Neuronetics, Inc. 3222 Phoenixville Pike Malvern, PA 19355
Primary Contact:	Robin Fatzinger, RAC Sr. Director, Regulatory Affairs Phone: 610-981-4027 Email: robin.fatzinger@neurostar.com
Secondary Contact:	Cory Anderson VP, R&D and Clinical Phone: 610-981-4104 Email: cory.anderson@neurostar.com
Device Trade Names:	NeuroStar, NeuroStar TMS Therapy System, NeuroStar Advanced Therapy System, NeuroStar Advanced Therapy for Mental Health
Device Common Name:	Transcranial Magnetic Stimulation System for Neurological and Psychiatric Disorders and Conditions
Classification:	21 CFR 882.5802
Product Code:	QCI
Predicate Devices:	Primary Predicate: MagVenture TMS Therapy System – for adjunctive treatment of OCD (K193006) Predicate: NeuroStar Advanced Therapy System (K201158, K161519, K160703, K133408, K130233, K083538, DEN060153/K061053)

Device Description / Technological Characteristics:

The NeuroStar Advanced Therapy System, for adjunctive treatment of OCD, 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. NeuroStar Advanced Therapy System is indicated as an adjunct for the treatment of adult patients who are suffering from Obsessive-Compulsive Disorder (OCD). NeuroStar Advanced Therapy System has previously obtained FDA clearance for treatment of major depressive disorder (MDD) in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode (K201158, K161519, K160703, K133408, K130233, K083538, DEN060153/K061053).

The subject device is substantially equivalent to the primary predicate device that was cleared under K193006. Neuronetics has implemented minor labeling enhancements to the software user interface and IFU to implement the OCD workflow. While the stimulation parameters have changed for OCD treatment, no changes alter the technical specifications of the subject device.

Consistent with the primary predicate and predicate devices, the proposed NeuroStar Advanced Therapy System, for adjunctive treatment of OCD, enables direct non-invasive activation of brain structures. 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 structure.

Intended 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 intended use is identical to that of the Primary Predicate Device.

Technological Characteristics and Substantial Equivalence:

The subject device, NeuroStar Advanced Therapy System, has the following similarities to the primary predicate (MagVenture TMS Therapy System - K193006) and predicate (NeuroStar Advanced Therapy System - K201158, K161519, K160703, K133408, K130233, K083538, DEN060153/K061053) devices:

- Principles of operation
- Design for delivery of Transcranial Magnetic Stimulation (TMS)
    - o Output stimulation parameters (pulse width, frequency range, pulse interval range, etc.)
- Materials

The proposed changes for the NeuroStar Advanced Therapy System, for adjunctive treatment of OCD, are limited to updates to the IFU and software for user interface and treatment stimulation parameters to facilitate safe and effective treatment of patients with OCD. The proposed changes are supported by information submitted in this premarket notification and with the following rationale:

- The subject device is substantially equivalent to the FDA-cleared MagVenture TMS Therapy System (K193006).
- The predicate device, NeuroStar Advanced Therapy System, was previously cleared by the FDA under K201158, K161519, K160703, K133408, K130233, K083538, and DEN060153/K061053.

The subject device changes are limited to updates to the IFU and software for user interface and treatment stimulation parameters to facilitate safe and effective treatment of patients with OCD. Therefore, the NeuroStar TMS Therapy System with the proposed changes to the treatment stimulation parameters and labeling is substantially equivalent to the predicate device.

The NeuroStar Advanced Therapy System, for adjunctive treatment of OCD, consists of components that are similar to those of the primary predicate device, with the exception of the treatment coil construction characteristics. The NeuroStar Advanced Therapy System coil is equivalent to the primary predicate device in terms of biocompatibility, design elements, such as cable lengths, coil materials, isolation design and functionalities, however, differs in cooling methods and coil winding configuration / surface area. All coils are subject to high-voltage tests and leakage current tests to ensure safety.

To establish substantial equivalency for the NeuroStar Advanced Therapy System coil, both modeling and performance testing was conducted. Measurements of the magnetic and electric fields of the MagVenture Cool D-B80 coil and NeuroStar coil were taken according to Section 4 of the FDA's Class II Special Controls Guidance document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems.

Measurements of the magnetic field distribution for the Cool D-B80 coil and the NeuroStar Advanced Therapy System coil were performed and determined that the magnetic spatial distribution is substantially equivalent. Both the NeuroStar and MagVenture coils are figure 8 designs, both allowing for deep and broad stimulation of the cortex. Information about magnetic field characteristics, including linearity of output level, magnetic field strength gradients, output waveform and magnetic field spatial distribution according to the Special Controls Guidance document, Section 4 as mentioned above were provided. The coil measurements are based on well-established scientific methods using standard scientific instrumentation.

Measurements of the electric field distribution for the Cool D-B80 coil and the NeuroStar Advanced Therapy System coil were performed and determined that the linearity of the electric field output and the electric field spatial distributions are substantially equivalent. The coil measurements are based on well-established scientific methods using standard scientific instrumentation.

Secondly, performance testing comparing the subject and primary predicate device was conducted to evaluate the equivalence in safety and performance based upon electric field distribution, stimulation volume, magnetic field distribution, and magnetic flux, pulse shape, and pulse timing as required in the FDA Special Controls Guidance Document. Results of the testing demonstrate substantial equivalence and confirm that no new safety or effectiveness issues are introduced.

Based on the measurements summarized above, it is therefore concluded, that the magnetic field and electric field properties of the NeuroStar coil are substantially equivalent to the primary predicate device, Cool D-B80.

Additionally, the subject device has been tested in accordance with IEC60601 Edition 3.1 and verified to comply with the specified permissible sound pressure levels and permissible thresholds for exposure defined by the Occupational Safety and Health Administration (OSHA).

These tests provide evidence that the NeuroStar Advanced Therapy system does not pose any risk for potential hearing reduction or loss in either patients or operators.

Performance Standards:
The NeuroStar Advanced Therapy System, for adjunctive treatment of OCD, has been tested and conforms with the following standards:

- ISO 13485:2016
- IEC60601-1
- IEC60601-1-2

The following tests were performed to validate the modifications to the device software and indications for use:

- Software verification and validation
- Performance Testing - Bench

In all instances, the subject device functions as intended and meets all the same acceptance as the primary predicate and predicate devices.

Non-Clinical Testing:
The contents of this 510(k) complies 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"*. The non-clinical performance testing of the components of NeuroStar Advanced Therapy System, for treatment of OCD, has been tested as required according to the Special Controls per 21 CFRH 882.5802.

Clinical Testing
This 510(k) does not contain any pivotal clinical trial data related to the new device. The substantial equivalency is established based on similar technological characteristics.

Comparison of Technological Characteristics

Specification	Subject Device	Predicate Device	Primary Predicate Device	Justification of Differences
	NeuroStar Advanced Therapy System (for adjunctive treatment of OCD)	**NeuroStar Advanced Therapy system (K201158, K161519, K160703, K133408, K130233, K083538, DEN060153/K061053)**	**MagVenture TMS Therapy System (K193006) Tonica Elektronik A/S, Denmark**	
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)	Not Applicable	The MagVenture TMS Therapy System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive- Compulsive Disorder (OCD)	No Difference
Energy Delivered and Performance	Treatment parameters:	Not Applicable	Treatment parameters:	
	Intensity: of Leg MT (Leg Motor Threshold) 100%		Intensity: of Leg MT (Leg Motor 100%	No Difference
	Repetition Rate: 20 Hz		Repetition Rate: 20 Hz	No Difference
	Train Duration: 2 sec		Train Duration: 2 sec	No Difference
	Inter-train-Interval: 20 secs		Inter-train- 20 secs	No Difference
	Number of trains: 50		Number of 50	No Difference
	Number of pulses: 2000		Number of 2000	No Difference
	Total duration: 18.3 min		Total duration: 18.3 min	No Difference
	Treatment area: Area of brain to be stimulated: Dorsomedial Prefrontal Cortex	Not Applicable	Treatment area: Area of brain to be stimulated:	No Difference

	Output Stimulation Parameters: Available Stimulation Intensity in terms of Standard Motor Threshold (SMT) units Range: 0.22 - 2.08 SMT Waveform: Biphasic	Output Stimulation Parameters: Available Stimulation Intensity in terms of Standard Motor Threshold (SMT) units Range: 0.22 - 2.08 SMT Waveform: Biphasic	Output Stimulation Parameters: Available Stimulation Intensity in terms of Standard Motor Threshold (SMT) units Range: 0 – 2.6 SMT Waveform: Biphasic	Similar
Design	The system consists of: 1. Mobile console 2. System software with GUI 3. Treatment chair 4. Head support system 5. Coil positioning system 6. Same Coil for both MT and treatment 7. Coil fixture 8. Data management system	The system consists of: 1. Mobile console 2. System software with GUI 3. Treatment chair 4. Head support system 5. Coil positioning system Same Coil for both MT and treatment 7. Coil fixture 8. Data management system	The system consists of: 1. Mobile console 2. System software with GUI 3. Treatment chair* 4. Head support system* 5. Coil positioning system 6. Same Coil for both MT and treatment 7. Coil fixture 8. Data management system *optional	No Difference
Coil	Bent figure 8 coil with ferromagnetic core	Bent figure 8 coil with ferromagnetic core	Figure 8 double-cone coil, Air Core	Both provide effective stimulation for targeted region based on performance testing.
Cooling	Air cooled. Used for both MT determination and treatment	Air cooled. Used for both MT determination and treatment	Liquid cooled Used for both MT determination and treatment.	Both sufficient for safety with treatment duty cycle based on performance testing.
Standards	Company complies with EN ISO 13485:2016.	Company complies with EN ISO 13485:2016.	Company complies with ISO 13485:2016.	No Difference
Electrical safety	Complies with IEC60601-1 Edition 3.1, and IEC60601-1-2:2014.	Complies with IEC60601-1 Edition 3.1, and IEC60601-1-2:2014.	Complies with IEC60601-1 v. 3.1, and IEC60601-1-2	No Difference

Conclusion:

The NeuroStar Advanced Therapy System has the same intended use and indications, principles of operation, and similar technological characteristics as the previously cleared primary predicate device. The minor differences noted in the technical characteristics between the coil assemblies do not raise any new or different questions of safety or effectiveness. Performance data demonstrates that the subject device is safe and effective for its intended use. Thus, the NeuroStar Advanced Therapy System, for adjunctive treatment of OCD, is substantially equivalent to the MagVenture TMS Therapy System – for adjunctive treatment of OCD.