December 10, 2021

Neuronetics, Inc
Fred Cowdery
Director, Regulatory Affairs and Qulaity Assurance
3222 Phoenixville Pike
Malvern, Pennsylvania 19355

Re: K213543
Trade/Device Name: NeuroStar TMS Therapy System, NeuroStar Advanced Therapy System, NeuroStar, NeuroStar Advanced Therapy for Mental Health
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulation system
Regulatory Class: Class II
Product Code: OBP
Dated: November 2, 2021
Received: November 8, 2021

Dear Fred Cowdery:

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

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)*

K213543

Device Name
NeuroStar Advanced Therapy System

Indications for Use *(Describe)*
The NeuroStar Advanced Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

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 (As required by Section 807.92)

Date Prepared: November 2, 2021

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

Contact Person:
Fred Cowdery
Director – Regulatory Affairs and Quality Assurance
Ph 610.981-4138
Email: fred.cowdery@neurostar.com

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

Device Name: Common: Transcranial Magnetic Stimulation System

Classification: 21 CFR 882.5802, Transcranial Magnetic Stimulation System for Neurological and Psychiatric Disorders and Conditions

Regulatory Class: Class II Medical Device

Product Code: OBP

Predicate Device(s): NeuroStar Advanced Therapy System, K201158,

Device Description / Technological Characteristics:

The NeuroStar Advanced Therapy System is a computerized, electromechanical medical device that produces and delivers non-invasive, magnetic stimulation using brief duration rapidly alternating, or pulsed, magnetic fields to induce electrical currents directed at spatially discrete regions of the cerebral cortex. This method of cortical stimulation by application of brief magnetic pulses to the head is known as Transcranial Magnetic Stimulation (TMS). NeuroStar Advanced Therapy is a non-invasive tool for the stimulation of cortical neurons for the treatment of adult patients with Major Depressive Disorder (MDD) who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode. NeuroStar Advanced Therapy is used for patient treatment by prescription only under the supervision of a licensed physician and can be used in both inpatient and outpatient settings including physician's offices, clinics, and hospitals. NeuroStar Advanced Therapy uses a well-understood property of physics regarding the law of electromagnetic induction, which states that a time-varying or moving magnetic field will induce an electric current in an adjacent conductive substance with the electric current traveling in a direction perpendicular to the motion of the magnetic field. NeuroStar Advanced Therapy uses a generated magnetic field as a vector for delivering an electrical current to a target conductor of interest, which in therapeutic application, is the brain. By using this method of delivering electrical current to the brain the electrical current produced in the brain can be delivered in an anatomically focused manner at discrete cortical areas of interest and can avoid areas of the brain that are not relevant for its therapeutic actions.

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

- Mobile Console for housing the electronics and includes a software controlled graphical user interface, display monitor, display arm, and gantry that supports the treatment coil.
- Ferromagnetic Coil for delivering treatment.
- Head Support System for positioning the treatment coil and includes a laser-guided alignment system
- Optional MT Cap for
- Multi-use consumable SenStar Treatment Link for contact sensing of the treatment coil with the patient's head and magnetic field quality control.
- TrakStar Patient Data Management System for recording patient data and includes a stand-alone computer and data management software

Proposed Change:
The proposed change to the NeuroStar Advanced Therapy System is the addition of the a single use wearable device, namely the MT Cap Accessory, which provides an optional method to aid in the Motor Threshold Hunt process (MT Hunt).

It is only worn during the MT Hunt (prior to the patient's first treatment session) as a guide to facilitate the hunt for the MT location.

The MT Cap outer surface contains a symmetrical grid printed with alternating colors, and includes two intersecting lines which indicate the MT Hunt starting point for coil positioning. The seam on the cap is aligned the patient's nasion and the edge of the cap is positioned above the patient's eyebrows.

The symmetrical grid printed on the outer surface of the MT Cap enables the physician to easily move the coil incrementally in the anterior and posterior directions without having to adjust the A/P Bar.

As pulses are delivered to the patient during the MT Hunt process, the treating physician monitors the patient hand for involuntary movement in exactly the same manner as the current method.

The SOA grid lines are then used to align the coil to deliver pulses in the SOA angle (i.e. medial/lateral directions). When each pulse is delivered, the treating physician is observing the patient hand for involuntary movement in exactly the same manner as the current method.

Intended Use:

The NeuroStar Advanced Therapy system is indicated for the treatment of Major Depressive Disorder in adult patients who failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.

Performance Standards:

The NeuroStar Advanced Therapy system has been tested and conforms with the following recognized consensus standards:

- IEC60601-1
- IEC60601-1-2
- ISO 10993-1:2018
- IEC 60601-1-6:2010, Edition 3.1

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 MT Cap was conducted according to ISO 10993-1:2018 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process.

Additionally, Usability testing was completed in accordance with IEC 60601-1-6:2010, Edition 3.1 and also following the FDA Guidance Document "Applying Human Factors and Usability Engineering to Medical Devices".

Clinical Testing:

There is no clinical testing required to support this submission.

Technical Comparison:

Device Feature	Subject Device, NeuroStar AdvancedTherapy System	Predicate Device, NeuroStar AdvancedTherapy System K201158	Substantial EquivalenceRationale
Intended Use	Major Depressive Disorder	Major Depressive Disorder	Same
Indications for Use	Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode	Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode	Same
Population	Adult patients	Adult patients	Same
Materials	Standard materials commonly used in the manufacture of electrical medical devices.	Standard materials commonly used in the manufacture of electrical medical devices.	Same

Device Feature	Subject Device, NeuroStar AdvancedTherapy System	Predicate Device, NeuroStar AdvancedTherapy System K201158	Substantial EquivalenceRationale
Design	Computerized, electromechanical medical devices that use integrated systems to deliver TMS therapy	Computerized, electromechanical medical devices that use integrated systems to deliver TMS therapy	Same
Energy Source	Power console with magnetic coil for delivery of magnetic energy	Power console with magnetic coil for delivery of magnetic energy	Same
Biocompatibility	Patient-contacting device components use standard materials compliant with ISO10993-1:2018 that are commonly used in consumer products and medical device applications.	Patient-contacting device components use standard materials compliant with ISO 10993-1:2018 that are commonly used in consumer products and medical device applications	Same
Electrical Safety EMC	IEC 60601-1 compliant IEC 60601-1-2 compliant	IEC 60601-1 compliant IEC 60601-1-2 compliant	Same

Device Feature	Subject Device, NeuroStar AdvancedTherapy System	Predicate Device, NeuroStar AdvancedTherapy System K201158	Substantial EquivalenceRationale
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	Same
Coil Type	Ferromagnetic Iron Core Internal Cooling Fan	Ferromagnetic Iron Core Internal Cooling Fan	Same
Coil Positioning System	Integrated into Head SupportSystem Laser-Aided Coil Placement	Integrated into Head SupportSystem Laser-Aided Coil Placement	Same
Treatment Quality Features	Magnetic Field Level Detection Coil Contact Sensing	Magnetic Field Level Detection Coil Contact Sensing	Same
Anatomical Sites	Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex	Same

Device Feature	Subject Device, NeuroStar AdvancedTherapy System	Predicate Device, NeuroStar AdvancedTherapy System K201158	Substantial EquivalenceRationale
Treatment Requirements	TMS Treatments 5 days per week for 4 to 6weeks Total of 20 to 30 treatment sessions	TMS Treatments 5 days per week for 4 to 6weeks Total of 20 to 30 treatment sessions	Same
Device Components	Mobile Console Ferromagnetic Coil for delivering treatment. Head Support System for coil positioning. MT Cap for coil positioning Multi-use disposable for contact sensing and magnetic field quality control. TrakStar System for recording patient data	Mobile Console Ferromagnetic Coil for delivering treatment. Head Support System for coil positioning. Multi-use disposable for contact sensing and magnetic field quality control. TrakStar System for recording patient data.	Different The addition of the MT Cap accessory is the subject of this special 510K
%MT Range	25% to 140% MT	25% to 140% MT	Same

Device Feature	Subject Device, NeuroStar AdvancedTherapy System	Predicate Device, NeuroStar AdvancedTherapy System K201158	Substantial EquivalenceRationale
Pulses per Second (PPS)Range	For Treatment: 1 to 30 PPS For MT Determination: 0.1 to 0.3 PPS	For Treatment: 1 to 30 PPS For MT Determination: 0.1 to 0.3 PPS	Same
Induced Electric Field at 2 cm at 1.0 SMT	135 V/m (Nominal)	135 V/m (Nominal)	Same
Pulse Type	Biphasic Sinusoid	Biphasic Sinusoid	Same
Pulse Width	185µS (Nominal)	185µS (Nominal)	Same
Treatment Protocols	Standard Treatment Level: 120% MT with allowable adjustments Repetition Rate: 10 PPS Stimulation Time: 4 sec. Inter-train Interval: As low as11 sec. Session Duration: As low as 18.75 min. Pulses per Session: 3000 Sessions per Week: 5	Standard Treatment Level: 120% MT with allowable adjustments Repetition Rate: 10 PPS Stimulation Time: 4 sec. Inter-train Interval: as low as11 sec. Session Duration: As low as 18.75 min. Pulses per Session: 3000 Sessions per Week: 5	Same

Device Feature	Subject Device, NeuroStar AdvancedTherapy System	Predicate Device, NeuroStar AdvancedTherapy System K201158	Substantial EquivalenceRationale
	NeuroBurst Treatment Level: 80 - 120% MT with allowable adjustments Stimulation Time: 2 sec. Inter-train Interval: 8 sec. Pulses per Burst: 3 pulses Interpulse Interval: 20 ms Pulses per Session: 600 Session Duration: 3.3 min Bursts per Second: 5 burstsAmplitude: 0.22-2.08 SMT (≤ 5% drop)	NeuroBurst Treatment Level: 80 -120% MT with allowable adjustments Stimulation Time: 2 sec. Inter-train Interval: 8 sec. Pulses per Burst: 3 pulses Interpulse Interval: 20 ms Pulses per Session: 600 Session Duration: 3.3 min Bursts per Second: 5 bursts Amplitude: 0.22-2.08 SMT (≤ 5% drop)	Same
Treatment Level Range	Standard Treatment 0.22 SMT to 2.08 SMTCalibrated linear output	Standard Treatment 0.22 SMT to 2.08 SMTCalibrated linear output	Same
	NeuroBurst Treatment 0.22 to 1.9 SMT 80-120% MT ≤ 5% drop	NeuroBurst Treatment 0.22 to 1.9 SMT 80-120% MT ≤ 5% drop	Same

Conclusion:

The NeuroStar Advanced Therapy System and the primary predicate device have the same indications for use and the same technological characteristics. The use of the optional MT Cap accessory does not raise any new questions of safety or effectiveness.