April 4, 2023

Neuronetics
Amanda Pentecost, Ph.D.
Regulatory Affairs Specialist
3222 Phoenixville Pike
Malvern, Pennsylvania 19355

Re: K230029
Trade/Device Name: NeuroStar Advanced Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP, QCI
Dated: January 4, 2023
Received: January 4, 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,

Pamela D. Scott -S

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)*
K230029

Device Name
NeuroStar Advanced Therapy System (Version 3.7)

Indications for Use *(Describe)*
The NeuroStar Advanced Therapy System is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode.

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.

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510(k) Summary

Date Prepared:	April 4, 2023
Applicant:	Neuronetics, Inc. 3222 Phoenixville Pike Malvern, PA 19355
Contact Person:	Amanda Pentecost, PhD Regulatory Affairs Specialist Phone: 610-640-4202, ext. 1132 Email: amanda.pentecost@neurostar.com
Secondary Contact:	Robin Fatzinger Sr. Director, Regulatory Affairs Phone: 610-640-4202, ext. 1064 Email: robin.fatzinger@neurostar.com
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 882.5805, 21 CFR 882.5802
Product Codes:	OBP, QCI
Primary Predicate Device:	NeuroStar Advanced Therapy System (K083538, K130233, K133408, K160703, K161519, K201158, and K220127) (Product Code: OBP)
Secondary Predicate Device:	NeuroStar Advanced Therapy System (K212289) (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

There are two proposed changes to the NeuroStar Advanced Therapy System that are the subject of this 510(k). The first proposed change introduces the capability to use wireless communication to transfer data between the NeuroStar System software and the TrakStar Patient Data Management System, as an alternative to using an ethernet cable to facilitate this transfer. The second proposed change allows for the alternative use of the Beam F3 treatment location method (herein: "Beam F3 method"), in addition to the current method that utilizes a location 5 cm away from the motor threshold within the dorsolateral prefrontal cortex (DLPFC) region of the brain. The Beam F3 method requires measuring different skull dimensions and uses these values to calculate the F3 treatment location, which is also located within the DLPFC. This 510(k) introduces software embedded into the NeuroStar System that performs these calculations as well as single-use measuring accessories. Once the F3 treatment location is determined, the treatment parameters and protocols remain the same as those used in the currently marketed NeuroStar Advanced Therapy System.

Indications for Use:

The NeuroStar Advanced Therapy System is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in

adult patients suffering from Major Depressive Disorder (MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode.

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 NeuroStar Advanced Therapy System has been tested and conforms to the following recognized consensus standards:

- ISO 10993-1
- ANSI AAMI ES60601-1 / IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-6

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." Non-clinical performance testing was performed according to the standards listed above.

Additionally, usability testing was completed in accordance with IEC 60601-1-6 and also following FDA Guidance Document: "Applying Human Factors and Usability Engineering to Medical Devices." Software was designed, developed, and tested in accordance with relevant FDA guidance documents, IEC 62304, and ISO 14971.

Clinical Testing:

There is no clinical testing required to support this submission.

Technological Comparison with Primary Predicate (Product Code: OBP):

	NeuroStar Advanced Therapy System (Subject Device)	NeuroStar Advanced Therapy System (Primary Predicate Device - K083538, K130233, K133408, K160703, K161519, K201158, and K220127)	Explanation of Differences
Indications for Use	The NeuroStar Advanced Therapy System is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode.	The NeuroStar Advanced Therapy System is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode.	No Difference
Intended Use	Major Depressive Disorder (MDD) and comorbid anxiety symptoms	Major Depressive Disorder (MDD) and comorbid anxiety symptoms	No Difference
Anatomical Sites	Left dorsolateral prefrontal cortex	Left dorsolateral prefrontal cortex	No Difference
Target Population	Adult patients	Adult patients	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	Ethernet cable	Different The addition of the wireless capability is part of the subject of this 510(k).
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 Internal cooling fan	Ferromagnetic Iron core Internal cooling fan	No Difference
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	5 days per week for 6 weeks with taper over 3 weeks (3 sessions first week, 2 sessions second week and 1 session third week) for total of 36 treatment sessions.	5 days per week for 6 weeks with taper over 3 weeks (3 sessions first week, 2 sessions second week and 1 session third week) for total of 36 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 • 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 • TrakStar System for recording patient data	Different The addition of the Beam F3 Treatment Pack is part of the subject of this 510(k).
%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	**Standard Treatment:** **Level:** 120% MT with allowable adjustments **Repetition Rate:** 10 PPS **Stimulation Time:** 4 s **Inter-train Interval:** As low as 11 s **Session Duration:** As low as 18.75 min **Pulses per Session:** 3000 **Sessions per Week:** 5 (Acute phase)	**Standard Treatment:** **Level:** 120% MT with allowable adjustments **Repetition Rate:** 10 PPS **Stimulation Time:** 4 s **Inter-train Interval:** As low as 11 s **Session Duration:** As low as 18.75 min **Pulses per Session:** 3000 **Sessions per Week:** 5 (Acute phase)	No Difference
	NeuroBurst Treatment: **Level:** 80-120% MT with allowable adjustments **Stimulation Time:** 2 s **Inter-train Interval:** 8 s **Pulses per Burst:** 3 **Interpulse Interval:** 20 ms **Session Duration:** 3.3 min **Pulses per Session:** 600 **Bursts per Second:** 5 **Amplitude:** 0.22-2.08 SMT (≤5% drop)	**NeuroBurst Treatment:** **Level:** 80-120% MT with allowable adjustments **Stimulation Time:** 2 s **Inter-train Interval:** 8 s **Pulses per Burst:** 3 **Interpulse Interval:** 20 ms **Session Duration:** 3.3 min **Pulses per Session:** 600 **Bursts per Second:** 5 **Amplitude:** 0.22-2.08 SMT (≤5% drop)	
Treatment Level Range	**Standard Treatment:** 0.22 to 2.08 SMT Calibrated linear output	**Standard Treatment:** 0.22 to 2.08 SMT Calibrated linear output	No Difference
	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	
Stimulation Time Pulse Train Duration Range	**Standard Treatment:** 1 PPS: 1 to 600 s > 1 PPS: 1 to 20 s	**Standard Treatment:** 1 PPS: 1 to 600 s > 1 PPS: 1 to 20 s	No Difference
	NeuroBurst Treatment: 1 to 10 s	**NeuroBurst Treatment:** 1 to 10 s	

Inter-train Interval Range	**Standard Treatment:** 1 PPS: 0 to 600 s >1 PPS: 10 to 60 s	**Standard Treatment:** 1 PPS: 0 to 600 s >1 PPS: 10 to 60 s	No Difference
	NeuroBurst Treatment: 1 to 60 s	**NeuroBurst Treatment:** 1 to 60 s	
Pulse per Treatment Session	**Standard Treatment:** Nominal: 3000 Maximum: 5000	**Standard Treatment:** Nominal: 3000 Maximum: 5000	No Difference
	NeuroBurst Treatment: Nominal: 600 Maximum: 2000	**NeuroBurst Treatment:** Nominal: 600 Maximum: 2000	
Pulses per Burst (PPB)	**NeuroBurst Treatment:** 1 to 5	**NeuroBurst Treatment:** 1 to 5	No Difference
Interpulse Interval	**NeuroBurst Treatment:** 20 to 2000 ms	**NeuroBurst Treatment:** 20 to 2000 ms	No Difference
Bursts per Second (BPS)	**NeuroBurst Treatment:** 0.1 to 20.0 Hz	**NeuroBurst Treatment:** 0.1 to 20.0 Hz	No Difference

Technological Comparison with Primary Predicate (Product Code: QCI):

	NeuroStar Advanced Therapy System (Subject Device)	NeuroStar Advanced Therapy System (Secondary Predicate Device - K212289)	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	Ethernet cable	Different The addition of the wireless capability is part of the subject of this 510(k).
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 Internal cooling fan	Ferromagnetic Iron core Internal cooling fan	No Difference
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 • 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	• Mobile Console • Ferromagnetic Coil for delivering treatment • Head Support System for coil positioning • 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 • TrakStar System for recording patient data	Different The addition of the Beam F3 Treatment Pack is part of the subject of this 510(k) and specific to the MDD indication. *Note: The Beam F3 Treatment Pack is 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

Conclusion:

The NeuroStar Advanced Therapy System and the primary/secondary predicate devices have the same intended uses and technological characteristics. The use of the optional wireless communication or Beam F3 treatment location features do not raise any different questions regarding safety or effectiveness.