July 14, 2022

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

Re: K220127
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: June 11, 2022
Received: June 14, 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 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)*
K220127

Device Name
NeuroStar, NeuroStar TMS Therapy System, NeuroStar Advanced Therapy System, NeuroStar Advanced Therapy for Mental Health

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.

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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510k Summary

510(k) Number:	K220127
Date Prepared:	14 July 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, Clinical Affairs & Product Development 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 Stimulator
Classification:	21 CFR 882.5805
Product Code:	OBP
Predicate Devices:	Primary Predicate: Brainsway Deep Transcranial Magnetic Stimulation (K210201) Predicate: NeuroStar Advanced Therapy System (K201158, K161519, K160703, K133408, K130233, K083538)

Device Description

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 System consists of a combination of hardware, software, disposable, and consumable supplies, which are required for the operation of the system. The basic configuration includes the following components:

- Mobile Console
- System Software
- Treatment Chair
- Head Support System
- TrakStar PC
- TrakStar Software

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 indications for use for the subject device (NeuroStar Advanced Therapy System) is identical to that of the Primary Predicate Device.

Technological Characteristics and Substantial Equivalence:

NeuroStar TMS Therapy system has previously obtained FDA clearance for treatment of major depressive disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode (K061053, K083538, K130233, K133408, K160703, K161519, K201158).

The subject device is substantially equivalent to the primary predicate device that was cleared under K210201. Neuronetics has implemented minor labeling changes to update the indications for use and clinical summaries. None of these changes alter the technical specifications for the subject device. Consistent with the primary predicate and predicate devices, the NeuroStar Advanced Therapy System enables non-invasive activation of brain regions.

The components of, and mechanisms of operation for, the subject device are identical to the

previously cleared predicate device, NeuroStar Advanced Therapy System (K061053, K083538, K130233, K133408, K160703, K161519, K201158). The performance characteristics, including the Electrical and Magnetic Field Distribution testing are the same as the previously cleared NeuroStar Advanced Therapy System. The subject device has the following similarities to the primary predicate (Brainsway Deep TMS; K210201) and predicate NeuroStar Advanced Therapy System:

- Principles of operation
- Design for delivery of Transcranial Magnetic Stimulation (TMS)
- Materials

The stimulation parameters (frequency, train duration, inter-train interval, number of trains, number of pulses, and total duration of treatment) of the subject device are different from those of the primary predicate. Substantial equivalence between the subject device and the primary predicate device was established based on clinical performance data.

The proposed changes for the NeuroStar Advanced Therapy System are limited to labeling updates, specifically to include the treatment of adult patients with MDD who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode and may exhibit comorbid anxiety symptoms. 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 Brainsway Deep TMS (K210201).
- The predicate device, NeuroStar Advanced Therapy System, was previously cleared by the FDA under DEN060153/K061053, K083538, K130233 and K133408, K160703, K160703, K161519, and K201158.
- The subject device changes remain limited to labeling revisions, in support of the reference to treatment of adult patients with MDD who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode and may exhibit comorbid anxiety symptoms. No other changes are made to the device or product labeling.

Supportive clinical data has been provided to support the substantial equivalence of the subject NeuroStar Advanced Therapy System in terms of safety and effectiveness for the expanded indications for use. Therefore, the NeuroStar TMS Therapy System with the proposed changes to the product labeling is substantially equivalent to the primary predicate and predicate devices.

Non-Clinical Testing:
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 has been tested and conforms with the following standards:

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

Additionally, 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 was conducted as required according to the standards listed above. All system components have been previously cleared by the FDA.

Clinical Performance Data:

Clinical performance data was provided to support the safety and effectiveness of the NeuroStar Advanced Therapy System device for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD), as described in the Indications for Use statement. The clinical performance data was based on 2 Randomized Controlled Trials (RCTs) (George et al. (2010), O'Reardon et al. (2007)) in a total of 491patients and on supportive data from a total of 874 patients in one open-label study and four observational studies (retrospective medical chart review), including a large-scale analysis of real-world data (RWD).

The 2007 O'Reardon study was designed to evaluate the safety and efficacy of the NeuroStar Advanced Therapy System for the treatment of adult patients with major depressive disorder (MDD) (N=301) who failed to receive benefit from 1 to 4 prior antidepressant medications verified by the ATHF. The 2010 study by George et al. was a company-independent, NIMH-funded trial designed to evaluate the safety and efficacy of TMS in adult patients (N=190) with moderate to severe MDD who failed to receive benefit from 1 to 4 prior antidepressant medications verified by the ATHF (George, et al, 2010). Clinical data from these two randomized sham-controlled trials were originally used to establish the safety and efficacy effectiveness of NeuroStar Advanced Therapy for the treatment of adult patients with MDD (DEN060153/K061053) and as such, patient demographics and depression outcomes are presented in detail in earlier sections.

For the 2007 O'Reardon study and the 2010 George study, the effect sizes were identical, 0.36 (Cohen's d), representing a low effect size for decreasing anxiety symptoms in this patient population when compared to Sham control. These effect sizes compare favorably to the effect size reported in two of the three RCTs (Levkovitz et al. (2015) – 0.34 and Kaster et al. (2018) – 0.36) which formed the basis for clearance of Brainsway Deep TMS™ System (K210201), the primary predicate device, for the indications for use in section referenced above.

In both RCT studies, the effectiveness of NeuroStar Advanced Therapy for the treatment of comorbid anxiety symptoms in adult patients with MDD and comorbid anxiety symptoms was assessed using the Hamilton-D anxiety/somatization factor (HAMD – A/S F) Scale. The HAMD – A/S F Scale is a validated scale comprising six anxiety-specific items from the HAMD-17 or the HAMD-24. In O'Reardon et al. (2007), evaluation of change on the HAMD – A/S F was an a priori defined secondary endpoint. In both trials, the

between-group difference in the mean change in HAMD – A/S F scores from baseline to the 6-week endpoint evaluation was statistically significant ($p<0.05$) in favor of the active treatment group.

Additional clinical evidence intended to support the safety and efficacy effectiveness of The NeuroStar Advanced Therapy System administered to the left dorsolateral prefrontal cortex (DFLPFC), as per the standard NeuroStar treatment protocol for MDD, in patients with MDD and comorbid anxiety symptoms included data from the following studies:

1) A retrospective analysis of medical records from 57 adult patients with major depressive disorder (MDD) and comorbid anxiety symptoms who received rTMS treatment with The NeuroStar Advanced Therapy System demonstrated a clinically significant reduction in anxiety symptoms over a 6-week period, as measured by the HAMD-21 – A/S F or Generalized Anxiety Disorder-7 (GAD-7) score. (Tunistra et al. (2022)).

2) A large-scale retrospective analysis of real-world data (RWD) derived from the TrakStar registry data of 664 patients who received the standard NeuroStar treatment protocol for MDD over a span of 13 years, beginning in 2008. This RWD was collected from patients across 75 TMS centers in the US. These 664 patient records were analyzed to determine the difference in measures of depression (PHQ-9 scores) and anxiety (GAD-7 scores) over a pre-post TMS treatment interval of 6 weeks. (TrakStar (2022) study).

   Patients included in this RWD study had a primary diagnosis of MDD, had received at least 20 treatments with NeuroStar Advanced Therapy to the left dorsolateral prefrontal cortex (DLPFC); were required to exhibit baseline moderate or greater depression, defined as a score on the Physician Health Questionnaire-9 (PHQ-9) ≥ 10, and baseline moderate or greater anxiety symptoms, defined as a score on the Generalized Anxiety Disorder-7 (GAD-7) ≥ 10. The average patient age was 47.4 ± 13.9 years, and 67.9% were female.

   A total of 65.5% of patients met the primary outcome measure for anxiety which was the proportion of subjects who achieved a 6+ point improvement (reduction) in the GAD-7 score at end of treatment relative to baseline. The mean change in GAD-7 scores from baseline to endpoint was -8.0 ± 5.7 ($p<0.0001$), and 34.0% of patients attained remission, with remission of anxiety symptoms defined as a score on the GAD-7 < 5 at study endpoint. These statistically significant and clinically meaningful improvements in anxiety symptoms were accompanied by comparable changes in depression scores on the PHQ-9.

   The TrakStar registry did not account for medication or other treatment change for MDD or symptoms of anxiety that may have occurred during the treatment phase.

Table 1: Study Design and Outcomes from NeuroStar RCTs, TrakStar Data and Supportive Literature

Study	Device(s)	Study Design	Population	Sample size	Outcome Measure(s)	Study Results
O'Reardon et al., 2008	NeuroStar	• RCT • Left-sided dorsolateral prefrontal cortex (DLPFC) rTMS Therapy per standard NeuroStar treatment protocol	• Mean age (years): - Active: 47.9 ± 11.0 - Sham: 48.7 ± 10.6 • Females: - Active: 55.5% - Sham: 48.7% • Primary diagnosis of MDD.	301: - Active:155 - Sham: 146	• HAMD-24 • HAMD-17 • HAMD AS/F (*a priori* defined secondary endpoint)	Comparison between active and sham TMS groups in the change from baseline to endpoint (6 weeks): Response Rate: ≥ 50% decrease in end score relative to baseline (6 weeks): HAMD 17: p<0.05 HAMD-24: p<0.05 Mean Change in Scores from Baseline to Endpoint: HAMD-17: p<0.01 HAMD-24: p<0.05 HAMD-17-AS/F: p<0.05 (p=0.023) Effect size (Cohen's d): 0.36
	NeuroStar	• RCT • Left-sided dorsolateral prefrontal cortex (DLPFC) rTMS Therapy per standard NeuroStar treatment protocol	• Mean age (years): - Active: 47.7 ± 10.6 - Sham: 46.5 ± 12.3 • Females: - Active: 63% - Sham: 51% • Primary diagnosis of MDD.	190: - Active:9 2 - Sham: 98	• HAMD-24 • HAMD AS/F	Comparison between active and sham TMS groups in the change from baseline to endpoint (6 weeks): Response Rate: ≥ 50% decrease in end score relative to baseline (6 weeks): HAMD-24: p<0.01 Remission: HAMD-24 < 10: p<0.05 Mean Change in Scores from Baseline to Endpoint (6 weeks): HAMD-17-AS/F: p<0.05: - Active: -1.3; = Sham: -0.4 Effect size (Cohen's d): 0.36

TrakStar (unpublished)	NeuroStar	• Retrospective chart review & analysis of RWD since 2008. • Left-sided DLPFC rTMS Therapy per standard NeuroStar treatment protocol.	• Adults 22-70 years; mean age of 47.4±13.9 years. • 67.9% female • Primary diagnosis of MDD. • Baseline score on the GAD-7 ≥ 10	664	• GAD-7 • PHQ-9	Response Rate: ≥ 6 point decrease in end score relative to baseline (6 weeks): PHQ-9: 58.9% GAD-7: 65.5% Remission: PHQ-9: < 5: 30.4% GAD-7 < 5: 34.0% Mean Change in Scores from Baseline to Endpoint (6 weeks): PHQ-9: -10.5 ± 6.7, p<0.0001 GAD-7: -8.0 ± 5.7: p<0.0001 Effect size (Hedges g): -1.4
Tuinstra, et al. 2022	NeuroStar	• Retrospective chart review and analysis of RWD over 3.5 years. • Left-sided dorsolateral prefrontal cortex (DLPFC) rTMS Therapy per standard NeuroStar treatment protocol	• Adults 18-77 years; mean age of 45.3±16.7 years. • 61% female • Primary diagnosis of Treatment Resistant Depressions (TRD). • 52% had at least one diagnosis of a comorbid anxiety disorder	77 57 had clinically significant anxiety symptoms	• HAMD-17 Anxiety Somatization Factor (AS/F) Subscale • GAD-7 • PHQ-9	Remission: HAMD AS/F < 7: 87.5% GAD-7 < 5: 22.6% Response Rate: ≥ 50% decrease in end score relative to baseline (6 weeks): HAMD AS/F: 50% GAD-7: 41.5% Clinically Significant Change: HAMD AS/F: final score ≤ 3.2: 37.5% GAD-7: mean change from baseline to endpoint ≥ 6: 41.5% Mean Change in Scores from Baseline to Endpoint (6 weeks): HAMD AS/F: -3.53, p<0.001 GAD-7: -5.32: p<0.001 Effect size (Hedges g): -0.777

Table 2: Substantial Equivalence Comparison

Specification	Subject Device K220127 NeuroStar Advanced Therapy System	Primary Predicate Device K210201 Brainsway Deep TMS System	Justification 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 Brainsway Deep TMS™ 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
Treatment Schedule	5 daily sessions per week for 6 weeks plus 6 taper sessions over 3 weeks (36 total sessions)	5 daily sessions for 4 weeks; bi-weekly sessions for 12 Weeks (optional maintenance treatments)	The difference in treatment schedule between the subject and predicate devices is dependent on the device treatment protocol; differences do not raise differences in safety or effectiveness based on clinical data. Clinical evidence for the subject device has been included and demonstrated safety and effectiveness for the intended use.

	Treatment parameters		**Treatment parameters**		
	Magnetic Field Intensity	120%	**Magnetic Field Intensity**	120%	No Difference
	Repetition Rate	10 Hz	**Repetition Rate**	20 Hz	While the frequency is different between the subject and predicate devices, they are appropriate and within safe limits based on the train duration and intensity for each as indicated in Table 2 in Section 4 of the Special Controls Guidance. Clinical evidence for the subject device has been included and demonstrated safety and effectiveness for the intended use.
Energy Delivered and Performance	**Train Duration**	4 sec	**Train Duration**	2 sec	While the train duration is different between the subject and predicate devices, they are appropriate and within safe limits based on the frequency and intensity for each as indicated in Table 2 in Section 4 of the Special Controls Guidance. Clinical evidence for the subject device has been included and demonstrated safety and effectiveness for the intended use.
	Inter-Train-Interval	11-26 secs	**Inter-Train-Interval**	20 secs	The difference between the inter-train-intervals is appropriate for each device design and treatment protocol. These differences do not raise different questions of safety or effectiveness based on non-clinical and clinical testing. Clinical evidence for the subject device has been included and demonstrated safety and effectiveness for the intended use.
	Number of Trains	75	**Number of Trains**	55	The difference between the number of trains is appropriate for

					each device design and treatment. protocol. This difference does not raise different questions of safety or effectiveness based on non-clinical and clinical testing. Clinical evidence for the subject device has been included and demonstrated safety and effectiveness for the intended use.
	Number of Pulses	3000	**Number of Pulses**	1980	The difference between the number of pulses is appropriate for each device design and treatment protocol. This difference does not raise different questions of safety or effectiveness based on non-clinical and clinical testing. Clinical evidence for the subject device has been included and demonstrated safety and effectiveness for the intended use.
	Treatment Duration	18.75 min	**Treatment Duration**	20.2 min	The difference between the treatment duration is appropriate for each device design and treatment protocol. This difference does not raise different questions of safety or effectiveness based on non- clinical and clinical testing. Clinical evidence for the subject device has been included and demonstrated safety and effectiveness for the intended use.
	Treatment area of brain to be stimulated: Left Dorsolateral Prefrontal Cortex		Treatment area of brain to be stimulated: Left Dorsolateral Prefrontal Cortex		No Difference
	Output Stimulation Parameters Available Stimulation Intensity in terms of Standard Motor Threshold (SMT) units		Output Stimulation Parameters: Available Stimulation Intensity in terms of Standard Motor Threshold (SMT) units		The differences between the SMT ranges are dependent on the device design and treatment

	Range: .22 – 2.08 Waveform: Biphasic	Range: 0.6-1.4 Waveform: Biphasic	protocols. Each range is within the therapeutic stimulation range of the device. The difference does not raise new issues of safety or effectiveness since the maximum (100%) output level is unchanged from the previously cleared Neuronetics predicate device. Clinical evidence for the subject device has been included and demonstrated safety and effectiveness for the intended use.
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 6. Same Coil for both MT and treatment 7. Coil fixture 8. Data management system	No Difference

Coil	Biphasic Figure 8 Coil with Ferromagnetic Core	Biphasic H-Coil with Air Core	Both coils rely on transcranial magnetic stimulation by means of repetitive pulse trains at predetermined frequency. Both coils use the same mechanism of action (electromechanical instrument that produces and delivers brief duration, pulsed magnetic fields to induce electrical currents in localized regions of the prefrontal cortex). Differences in design do not raise different questions of safety or effectiveness as demonstrated by the clinical evidence presented within the 510(k). Clinical evidence for the subject device has been included and demonstrated safety and effectiveness for the intended use.
Cooling	Air cooled. Used for both MT determination and treatment	Liquid cooled Used for both MT determination and treatment	The H-Coil uses liquid cooling to maintain safe operating temperatures. The iron core figure-8 coil uses air cooling to maintain safe operating temperatures. Both methods of cooling are sufficient for the specific design. The differences do not raise different questions of safety or effectiveness as demonstrated by the non-clinical and clinical testing provided within the 510(k). Clinical evidence for the subject device has been included and demonstrated safety and effectiveness for the intended use.
Quality & Risk Standards	Company complies with ISO 13485:2016 and ISO 14971	Company complies with ISO 13485:2016 and ISO 14971	No Difference
Electrical Safety & Electromagnetic Compatibility	Complies with IEC60601-1 and IEC60601-1-2	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 primary predicate device and the previously cleared predicate device. The differences noted in the technical characteristics do not raise different questions of safety or effectiveness. Clinical performance data demonstrates that the subject device is safe and effective for its intended use. Thus, the NeuroStar Advanced Therapy System is substantially equivalent to the primary predicate and predicate devices.