



December 13, 2023

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

Re: K233621

Trade/Device Name: NeuroStar Advanced Therapy System (Version 3.8)
Regulation Number: 21 CFR 882.5805, 21 CFR 882.5802
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP, QCI
Dated: November 10, 2023
Received: November 13, 2023

Dear Amanda 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K233621

Device Name

NeuroStar Advanced Therapy System (Version 3.8)

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

<u>Date Prepared:</u>	November 10, 2023
<u>Applicant:</u>	Neuronetics, Inc. 3222 Phoenixville Pike Malvern, PA 19355
<u>Contact Person:</u>	Amanda Pentecost, PhD Sr. Regulatory Affairs Specialist Email: amanda.pentecost@neurostar.com
<u>Secondary Contact:</u>	Robin Fatzinger, RAC Sr. Director, Regulatory and Medical Affairs Email: robin.fatzinger@neurostar.com
<u>Device Trade Name:</u>	NeuroStar NeuroStar TMS Therapy System NeuroStar Advanced Therapy System NeuroStar Advanced Therapy System for Mental Health
<u>Device Common Name:</u>	Transcranial Magnetic Stimulator
<u>Classifications:</u>	882.5805, 882.5802
<u>Product Codes:</u>	OBP, QCI
<u>Primary Predicate Device:</u>	NeuroStar Advanced Therapy System: K083538, K130233, K133408, K160703, K161519, K201158, K220127, and K230029 (Product Code: OBP)
<u>Secondary Predicate Device:</u>	NeuroStar Advanced Therapy System: K212289 and 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 or Headrest
- SenStar® Connect Treatment Link & SenStar® Treatment Link
- Treatment Pack (for use with the SenStar® Connect Treatment Link)
- MDD MT Cap and OCD MT Cap
- TrakStar™ Patient Data Management System
- D-Tect™ MT Accessory
- NeuroSITE

Proposed Change:

The purpose of this 510(k) submission is to introduce the following new features and accessories of the NeuroStar Advanced Therapy System, version 3.8:

1. A simplified Headrest will replace the patient comfort-related features of the current Head Support System.
2. The NeuroSITE coil positioning accessory will replace the coil position measuring functions of the current Head Support System. This accessory will be used to navigate to and record the MT and treatment locations.
3. The NeuroStar System Software, version 3.8 introduces software allows for recording, saving, and displaying the patient's unique MT and treatment location based on the coil position measurements taken using the NeuroSITE.

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 and accessories have been tested and conform to the following recognized consensus standard:

- 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. Software was designed, developed, and tested in accordance with relevant FDA guidance documents, IEC 62304 and ISO 14971.

To summarize, the results of verification and validation testing confirmed that the NeuroSITE and Headrest can successfully be used with the NeuroStar System software to record, save, and display the patient's MT and treatment locations in a manner that is equivalent to the current Head Support System.

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 NeuroSITE, Headrest, or updated NeuroStar System software that supports these features does not raise any different questions regarding safety or effectiveness.

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	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 Internal cooling fan	Ferromagnetic Iron core Internal cooling fan	No Difference
Coil Positioning System	NeuroSITE	Integrated into Head Support System Laser-aided coil placement	Different The replacement of the Head Support System and laser with the Headrest and NeuroSITE as part of the NeuroStar Advanced Therapy System, version 3.8 is the subject of this 510(k). This technology change does not introduce any new risks. Engineering and Human Factors testing had demonstrated that the treatment location is equivalent whether using the Head Support System or the NeuroSITE and clinical outcomes will be the same.
Treatment Schedule	5 days per week for 6 weeks with taper over 3 weeks (3 sessions first week, 2 sessions second	5 days per week for 6 weeks with taper over 3 weeks (3 sessions first week, 2 sessions second	No Difference

	week and 1 session third week) for total of 36 treatment sessions.	week and 1 session third week) for total of 36 treatment sessions.	
Device Components	<ul style="list-style-type: none"> Mobile Console Ferromagnetic Coil for delivering treatment Headrest and NeuroSITE for patient comfort and coil positioning Positioning cushions and Head Side Pad for patient positioning and comfort (MDD) MT Cap and OCD 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 	<ul style="list-style-type: none"> Mobile Console Ferromagnetic Coil for delivering treatment Head Support System for patient comfort and coil positioning Positioning cushions and Head Side Pad for patient positioning and comfort (MDD) MT Cap and OCD 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 	<p>Different</p> <p>The replacement of the Head Support System and laser with the Headrest and NeuroSITE as part of the NeuroStar Advanced Therapy System, version 3.8 is the subject of this 510(k).</p> <p>This technology change does not introduce any new risks. Engineering and Human Factors testing had demonstrated that the treatment location is equivalent whether using the Head Support System or the NeuroSITE and clinical outcomes will be the same.</p> <p><i>*Note: The OCD MT Cap is not intended to be used in the MDD MT determination process.</i></p>
%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 μ S (Nominal)	185 μ S (Nominal)	No Difference
Treatment Protocols	<p>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)</p>	<p>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)</p>	No Difference
	<p>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 (\leq5% drop)</p>	<p>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 (\leq5% drop)</p>	
Treatment Level Range	<p>Standard Treatment: 0.22 to 2.08 SMT Calibrated linear output</p>	<p>Standard Treatment: 0.22 to 2.08 SMT Calibrated linear output</p>	No Difference
	<p>NeuroBurst Treatment: 0.22 to 1.9 SMT 80-120% MT \leq5% drop</p>	<p>NeuroBurst Treatment: 0.22 to 1.9 SMT 80-120% MT \leq5% drop</p>	
	<p>Standard Treatment: 1 PPS: 1 to 600 s</p>	<p>Standard Treatment: 1 PPS: 1 to 600 s</p>	No Difference

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

Technological Comparison with Secondary Predicate (Product Code: QCI)

	NeuroStar Advanced Therapy System (Subject Device)	NeuroStar Advanced Therapy System (Secondary 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	NeuroSITE	Integrated into Head Support System Laser-aided coil placement	Different The replacement of the Head Support System and laser with the Headrest and NeuroSITE as part of the NeuroStar Advanced Therapy System, version 3.8 is the subject of this 510(k). This technology change does not introduce any new risks. Engineering and Human Factors testing had demonstrated that the treatment location is equivalent whether using the Head Support System or the NeuroSITE and clinical outcomes will be the same
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/Accessories	Mobile Console • Ferromagnetic Coil for delivering treatment • Headrest and NeuroSITE for patient comfort and coil positioning • Positioning cushions and Head Side Pad for patient positioning and comfort	• Mobile Console • Ferromagnetic Coil for delivering treatment • Head Support System for patient comfort and coil positioning • Positioning cushions and Head Side Pad for patient positioning and comfort	Different The addition of the Headrest and NeuroSITE as part of the NeuroStar Advanced Therapy System, version 3.8 is

	<ul style="list-style-type: none"> • (MDD) MT Cap and OCD 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 	<ul style="list-style-type: none"> • (MDD) MT Cap and OCD 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 	<p>the subject of this 510(k). This technology change does not introduce any new risks. Engineering and Human Factors testing had demonstrated that the treatment location is equivalent whether using the Head Support System or the NeuroSITE and clinical outcomes will be the same.</p> <p><i>*Note: The (MDD) MT Cap and D-Tect MT Accessory are not intended to be used in the OCD MT determination process.</i></p>
%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	Level: 100% foot motor threshold level Repetition Rate: 20 PPS Stimulation Time: 2 s	No Difference

	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	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	
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