March 17, 2025

The Magstim Company Limited
Alan Yik
Senior Regulatory Affairs Specialist
Spring Gardens
Whitland
Carmarthenshire, SA34 0HR
United Kingdom

Re: K243869
Trade/Device Name: Horizon® 3.0 TMS Therapy System (Horizon 3.0 Inspire); Horizon® 3.0 TMS Therapy System (Horizon 3.0 with StimGuide Pro); Horizon® 3.0 TMS Therapy System (Horizon 3.0)
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulation system
Regulatory Class: Class II
Product Code: OBP
Dated: December 17, 2024
Received: December 17, 2024

Dear Alan Yik:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

PAMELA D. SCOTT -S

Digitally signed by PAMELA D. SCOTT -S
Date: 2025.03.17 22:31:20 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243869

Device Name

Horizon® 3.0 TMS Therapy System (Horizon 3.0 Inspire);
Horizon® 3.0 TMS Therapy System (Horizon 3.0 with StimGuide Pro);
Horizon® 3.0 TMS Therapy System (Horizon 3.0)

Indications for Use *(Describe)*

For Adults: Horizon 3.0 TMS Therapy Systems are indicated for the treatment of Major Depressive Disorder (MDD) in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode, as well as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

For Adolescents: Horizon 3.0 TMS Therapy Systems are indicated as an adjunct for the treatment of MDD in adolescent patients (age 15-21).

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.

Horizon 3.0 TMS Therapy System

510(k) Summary

510(k) Summary

A. Contacts Details

Applicant Name:	The Magstim Company Limited
Applicant Address:	Spring Gardens Whitland Carmarthenshire SA34 0HR United Kingdom
Applicant Contact Telephone:	+44 1994240798
Applicant Contact:	Mr. Alan Yik
Applicant Contact Email:	ayik@welcony.com

B. Device Name

Device Trade Name:	Horizon® 3.0 TMS Therapy System (Horizon 3.0 Inspire); Horizon® 3.0 TMS Therapy System (Horizon 3.0 with StimGuide Pro); Horizon® 3.0 TMS Therapy System (Horizon 3.0)
Common Name:	Repetitive transcranial magnetic stimulation system
Classification Name:	Transcranial Magnetic Stimulator
Regulation Number:	882.5805
Product Code(s):	OBP, QCI - 21 C.F.R. § 882.5802

C. Legally Marketed Predicate Devices

Table 1 – List of Predicate Devices

Predicate#	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231926	NeuroStar Advanced Therapy System	OBP
K241518	Horizon® 3.0 TMS Therapy System (Horizon 3.0 Inspire); Horizon® 3.0 TMS Therapy System (Horizon 3.0 with StimGuide Pro); Horizon® 3.0 TMS Therapy System (Horizon 3.0)	OBP
K232235	Magstim® Horizon® 3.0 TMS Therapy System; Horizon® 3.0 System; Horizon® 3.0; Horizon® 3.0 with Navigation; Horizon® 3.0 with StimGuide Pro	OBP

Horizon 3.0 TMS Therapy System

510(k) Summary

D. Device Description Summary

The Horizon® 3.0 TMS 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").

The Horizon® 3.0 TMS Therapy System is a non-invasive tool for the stimulation of cortical neurons for the treatment of

- Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode
- as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).
- as an adjunct for the treatment of Major Depressive Disorder in adolescent patients (age 15-21)

The Horizon® 3.0 TMS Therapy System is used for patient treatment by prescription only under the supervision of a licensed physician. It can be used in both inpatient and outpatient settings, including physicians' offices, clinics, and hospitals.

The Horizon® 3.0 TMS Therapy System configurations are an integrated system consisting of a combination of hardware, software, and accessories.

The Horizon® 3.0 TMS Therapy System is offered in three configurations:

- Horizon 3.0 Inspire (Cleared under K241518).
- Horizon 3.0 (Cleared under K232235, K223154, K222171 and K211389).
- Horizon 3.0 with StimGuide Pro (Cleared under K232235).

The three tiers of system offer equivalent safety and effectiveness with the main purpose allowing for physician offices, clinics and hospitals to choose a configuration that suits the organizational needs and provide different entry levels to promote the accessibility of TMS Therapy Treatments to health delivery organizations.

All three configurations have identical intended use/indications for use, common specifications, equivalent performance and equivalent composition. All three devices share equivalent technological characteristics and principles of operation.

All configurations are composed from the following main components:

- Stimulating Unit & Power Supply
- User Interface
- Applicating Coil for Motor Threshold
- Applicating Coil for Treatment Delivery
- System and Applicating Coil Cart and Holding Arm

The Horizon 3.0 with StimGuide Pro specifically includes a stereotactic infrared tracking system for aiding coil positioning.

Horizon 3.0 TMS Therapy System

510(k) Summary

E. Intended Use/ Indications for Use

For Adults: Horizon 3.0 TMS Therapy Systems are indicated for the treatment of Major Depressive Disorder (MDD) in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode, as well as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

For Adolescents: Horizon 3.0 TMS Therapy Systems are indicated as an adjunct for the treatment of MDD in adolescent patients (age 15-21).

F. Indications for Use Comparison

The indications for use for the subject device and the primary predicate device (K231926) are equivalent.

The reference devices K241518 and K232235, which are identical in design, technological features and performance, have been previously cleared for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode, as well as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

The subject device indications for use have been updated to include the additional indication for the treatment, as an adjunct, for the treatment of Major Depressive Disorder (MDD) in adolescent patients (Age 15-21).

The performance data provided within this submission - such as the comparison of device electric and magnetic field output - demonstrate why the expansion of the indications to include the adjunct treatment of MDD in adolescent patients does not raise any differing questions of safety and effectiveness.

G. Technological Comparison

Introduction:
The Horizon® 3.0 TMS Therapy System is offered in three system configurations:
Horizon 3.0, Horizon 3.0 with StimGuide Pro and Horizon 3.0 Inspire.

All system configurations feature the same core components and operating principles that drive the device. All three configurations have identical intended use/indications for use, common specifications and equivalent performance compare with the primary predicate NeuroStar Advanced Therapy System.

Principles of Operation: Horizon 3.0 TMS Therapy System is identical to the primary predicate device in terms of principles of operation. Horizon 3.0 TMS Therapy System is capable of delivering

and provides the same recommended treatment protocols (rTMS and iTBS) as the primary predicate device.

The method for coil positioning is also equivalent to the primary predicate, with the Horizon 3.0 following the same principle of the statistical distance from the Motor Threshold (MT) Hotspot to the target area based on the chosen treatment (5.5cm from MT Hotspot, Left Dorsolateral Prefrontal Cortex, for MDD).

The principles of operation with respect to MT Determination remain identical to the primary predicate device - either by using visual qualitative monitoring for APB response or quantitative data provided by EMG.

In summary, the principles of operation of the subject Horizon 3.0 TMS Therapy System substantially equivalent to the primary predicate device configurations - NeuroStar Advanced Therapy System.

Technological Characteristics:
The subject device remains unchanged compare with the reference devices cleared by FDA under K241518 and K232235. The basic design of the subject device is substantially equivalent to the design of the primary predicate device cleared under K231926, as all configurations are based on applying transcranial magnetic stimulation by means of repetitive pulse trains at a predetermined frequency. Both systems in all configurations use the same mechanism of action, i.e. an electromechanical instrument that produces and delivers brief duration, rapidly alternating (pulsed) magnetic fields to induce electrical currents in localized regions of the prefrontal cortex.

Whilst the treatment coil construction characteristics in the subject device – Ez Cool Coil, Air Film Coil (Cleared in K232235 and K241518) and the primary predicate device – Neuronetics Coil are different, the magnetic field characteristics of the coils are equivalent which is pertinent to treatment delivery effectiveness. Comparison of the magnetic field characteristics, output waveform, magnetic/ electric field spatial distribution and magnetic field strength gradient was conducted between the Ez Cool Coil, Air Film Coil and Neuronetics Coil. The comparison shows that the Horizon Air Film Coil and Horizon 3.0 E-z Cool Coil is equivalent to the predicate device and does not raise any differing questions of safety or effectiveness when used as an adjunct for the treatment of adolescents (age 15 - 21) with MDD.

The performance evaluation measured for all coils in a precise setup, where a measuring probe for measuring the induced voltage was placed inside a phantom head model filled with a physiologic saline solution. The shape of the phantom head model is a representation of the human scalp and the saline solution provided a representation of the conductivity of the human brain. The measurements included magnetic field characteristics, output waveforms, magnetic/electric field spatial distribution and magnetic field strength gradient. Measurements were obtained to a depth of 3cm which was chosen as it encompasses the area and the typical depth required for determining Motor Thresholds as per the principles of operation for MDD treatments (2cm). The results from the evaluation demonstrated that all coils are substantially equivalent at the clinically relevant depth of 2-3cm.

Both the Horizon Air Film Coil and Ez Cool Coil have also been tested and found compliant to

60601-1 and 60601-1-2 testing for Electrical, Electromagnetic Compatibility, Thermal and Mechanical safety. Further, the coils materials of the patient contacting parts are identical to those which have been previously cleared under K241518 and K232235 and are in compliance with 10993 series applicable standards.

As can be seen from the summary above - technologically the Horizon 3.0 TMS Therapy System is very similar, and in some cases identical, to the primary predicate device. Despite of the differences of technological features illustrated above, both the subject device and primary predicate have the same core principles, technology, safety and effectiveness.

The design of all configurations in the subject device have been appropriately verified and conforms to the same safety standards as the primary predicate device such as IEC 60601-1, IEC 60601-1-2, IEC 60601-1-8, IEC 62366-1, AAMI/ANSI HE75, ISO 10993-1, ISO 14971 for electrical safety, thermal safety, mechanical safety, EMC, human factors, alarm systems and biocompatibility. Including IEC 62304, AAMI TIR57 and AAMI TIR97 for software and security. Security testing of the Horizon 3.0 TMS Therapy System such as Security Requirement, Threat Mitigation and Vulnerability testing was performed and documented in accordance with FDA guidance to demonstrate subject device is as secure as the primary predicate device.

The recommended treatment protocol as an adjunctive treatment for MDD on adolescent patient (age 15 – 21) is equivalent to that of the primary predicate device. This is further described below in **Table 2.**

Horizon 3.0 TMS Therapy System

510(k) Summary

Table 2: Horizon® 3.0 TMS Therapy System MDD Treatment Specifications Comparison Against Predicate Device

		Horizon® 3.0 TMS Therapy System (Subject of this submission)	**NeuroStar Advanced Therapy System** (K231926) (Primary Predicate)	**Horizon® 3.0 TMS Therapy System** (K232235, K241518) (Reference device)
Standard Treatment Protocol	**Magnetic Field Intensity**	120% of the MT	120% of the MT	120% of the MT
	Frequency	10 Hz	10 Pulse per second	10 Hz
	Train duration	4 sec (Note: this duration falls below the Maximum Safe Train Duration Limits for Avoiding Seizures, per the FDA Guidance for rTMS Systems)	4 sec	4 sec (Note: this duration falls below the Maximum Safe Train Duration Limits for Avoiding Seizures, per the FDA Guidance for rTMS Systems)
	Inter-train interval	11 to 26 sec	As low as 11 s	11 to 26 sec
	Number of trains	75	75	75
	Magnetic Pulses per Session	3000	3000	3000
	Treatment Session Duration	18.8 to 37.5 minutes	As low as 18.75 minutes	18.8 to 37.5 minutes
	Sessions/week	5	5	5
	Treatment Schedule	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks
	Area of brain to be stimulated	Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex
iTBS Treatment Protocol	**Stimulation Intensity**	120% of the MT	80 – 120% of the MT	120% of the MT
	Repetition Rate	50 Hz (5 pulses per sec)	50 Hz (5 pulses per sec)	50 Hz (5 pulses per sec)
	Train Duration	2 sec	2 sec	2 sec
	Inter-train Interval	8 sec	8 sec	8 sec
	Burst Pulses	3	3	3
	Bursts	200	200	200
	Inter Pulse interval	20 msec	20 msec	20 msec
	Number of trains	20	/	20
	Number of Pulses per Session	600	600	600
	Treatment Session Duration*	3 minutes 9 seconds	3.3 minutes	3 minutes 9 seconds
	Sessions/week	5	5	5
	Treatment Schedule	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks
	Area of brain to be stimulated	Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex

In conclusion - the Horizon® 3.0 TMS Therapy System with the addition of the patient group for the treatment, as an adjunct, of MDD to adolescent (age 15 – 21) does not raise any new or differing questions of safety or effectiveness and are substantially equivalent to the primary predicate NeuroStar Advanced Therapy System.

H. Non-Clinical and/or Clinical Tests Summary & Conclusions

Performance testing of the Horizon® 3.0 TMS Therapy System demonstrates that the device performs as intended for the safe and effective treatment of MDD, as an adjunct, for adolescent patients (age 15 – 21), and is therefore substantially equivalent to the primary predicate device NeuroStar Advanced Therapy System. The following nonclinical testing within this submission is relied upon for a determination of substantial equivalence:

Electromagnetic Compatibility in accordance with IEC 60601-1-2 - The Horizon 3.0 TMS Therapy System has been tested and found compliant to the requirements of IEC 60601-1-2 to demonstrate an equivalent level of Electromagnetic Compatibility as the primary predicate device. Electrical & Mechanical Safety in accordance with IEC 60601-1 - The Horizon 3.0 TMS Therapy System has been tested and found compliant to the requirements of IEC 60601-1 (including IEC 60601-1-6 and IEC 60601-1-8) to demonstrate an equivalent level of Electrical and Mechanical safety as the primary predicate device.

Thermal Safety in accordance with IEC 60601-1 - The Horizon 3.0 TMS Therapy System has been tested and found compliant to the requirements of IEC 60601-1 (including IEC 60601-1-6 and IEC 60601-1-8). Additional testing was performed to ensure that the Horizon Air Film Coil and Horizon 3.0 Ez Cool Coil can execute OCD, iTBS and rTMS protocols at worst-case ambient conditions without resulting in excessive temperatures.

Software Verification & Validation (IEC 62304, FDA Software Guidance) - Software has been developed in a structured manner following IEC 62304. Software lifecycle documentation demonstrates appropriate function of software and demonstrates the software cannot contribute to any unacceptable risk.

Usability/Human Factors Engineering (IEC 60601-1-6, IEC 62366-1, ANSI/AAMI HE75) - A human factors evaluation demonstrates appropriate human factors and usability of the Horizon® 3.0 TMS Therapy System device configurations for its intended use and demonstrates that the device is free from any unacceptable use related risks.

Magnetic Pulse Output Testing and Magnetic and Electrical Field Testing (Special Controls: 21 C.F.R. § 882.5802, 21 C.F.R. § 882.5805 and FDA Guidance “Repetitive Transcranial Magnetic Stimulation (rTMS) Systems – Class II Special Controls Guidance for Industry and FDA Staff” – July 26, 2011) - The electric field distribution produced by the subject coils and predicate coil in a human head phantom model filled with physiologic saline solution were measured for comparison. Values of the Magnetic and Electric field were obtained by measuring induced voltage into a measuring probe inside a phantom head model filled with a physiologic saline solution. The results demonstrated equivalent Power Outputs, Electric Fields and Magnetic Fields between the subject devices configuration applicating coil and the primary predicate device configuration applicating coil.

Safety Feature Testing (IEC 60601-1) - IEC 60601-1 testing exercises many fault scenarios to ensure appropriate safety features are maintained. System level testing documented as part of the software verification and validation also exercises the various interlocks with respect to safety features. Testing includes deliberately introducing failure modes to test multiple fault conditions, such as disabling a software check and ensuring a hardware backup interlock is active.

Acoustic Testing (IEC 60601-1) - Acoustic testing of the system under a simulated use scenario demonstrates the Horizon 3.0 TMS Therapy System with the Horizon Air Film Coil and Horizon 3.0 Ez Cool Coil do not reach excessive/unacceptable noise levels.

Clinical Testing - Not Applicable

Based on the above nonclinical testing – it can be concluded that the subject Horizon 3.0 TMS Therapy System substantially equivalent to the primary predicate device cleared under K231926. There is no change on the design of the all the configurations since the 510(k) clearance K241518 and K232235, which are the references device in the submission.

Electromagnetic Compatibility was demonstrated to be the same as the primary predicate device through compliance to IEC 60601-1-2. The test plan executed to evaluate the subject devices utilized the standard performance criteria used for EMC testing and therefore demonstrates a substantial equivalence of the subject Horizon 3.0 TMS Therapy System to the primary predicate device.

Electrical, Mechanical and Thermal safety was demonstrated through the application of IEC 60601-1. The subject Horizon 3.0 TMS Therapy System was found to be compliant to the standard. Further, in-house device specific protocol testing determined that for rTMS and iTBS treatment protocols under reasonable worst-case simulated ambient conditions (80% - 100% of machine output, at 30°C ambient room temperature) - the Horizon 3.0 TMS Therapy System with the Horizon Air Film coil and Horizon 3.0 E-z Cool Coil could perform the recommended protocols safely and effectively - equivalent to the primary predicate device with the Neuronetics Coil.

Software Verification and Validation was performed on the subject Horizon 3.0 TMS Therapy System to demonstrate the software behaviour is consistent and compatible across all configurations of the Horizon® 3.0 TMS Therapy System and fulfil its intended use. The testing also included cybersecurity testing to ensure the subject device configurations are as secure as the primary predicate device configurations.

Human Factors and Usability Engineering processes demonstrate the Horizon 3.0 TMS Therapy System is substantially equivalent to the primary predicate device configurations for its intended use in terms of human factors and usability, and demonstrates that the device is free from any unacceptable use related risks. The consistency of workflows, User Interfaces and components of known provenance between all configurations of the device promote a healthy usability profile for all system configurations.

Magnetic and Electric Field Testing demonstrated that the applicating coil of the subject device configurations - the Horizon Air Film Coil and Horizon 3.0 E-z Cool Coil, are substantially equivalent

to the applicating coil of the primary predicate device configuration. Values of the Magnetic and Electric field were obtained by measuring induced voltage into a measuring probe inside a phantom head model filled with a physiologic saline solution, with a total volume of 4cm x 3cm x 3cm and a resolution of 5mm.

Key characteristics of the field output were equivalent between coils; such as the required stimulator output/operating voltage, field spatial distribution, E-Field decay, output waveforms and magnetic field strength and rate of change. This is especially apparent at the clinically relevant depths of stimulation - where the values of the characteristics of coils were virtually identical.

The Air Film Coil and E-z Cool Coils used by the subject have been legally marketed for the treatment of MDD in adults since K143531 and K180907 respectively.

K143531 also used the Neuronetics Device and applicating coil as the primary predicate for the original introduction to market - where substantial equivalence between the Air Film Coil and Neuronetics device was demonstrated. This testing was re-performed and is documented within this submission to re-affirm the determination of substantial equivalence between the output characteristics of the subject device and primary predicate.

Further, the E-z Cool Coil has been recently compared with the Neuronetics and was deemed substantially equivalent in K222171 and K223154.

Finally, the Air Film Coil and E-z Cool Coil were compared first in K180907 and then most recently in the latest submission of the subject device (K241518) to each other and deemed substantially equivalent.

As a result - all three coils have been deemed substantially equivalent to each other for safe and effective stimulation at depths of 2-3cm which is in the clinically relevant area for the proposed indications for use.

This submission collects all this data together to provide a comprehensive comparison and demonstration of substantial equivalence of the subject device (including it's configurations) to the primary predicate device for the proposed indications for use.

Safety Feature Testing ensured all fault scenarios and safety features tested complies to IEC 60601-1. The testing provided within this submission demonstrates that there is substantial equivalence of safety features amongst all device configurations.

Acoustic Testing in simulated use conditions (Recommended Protocols at maximum machine output) for the subject Horizon 3.0 TMS Therapy System demonstrated the system with Horizon Air Film Coil and Horizon 3.0 E-z Cool Coil does not reach excessive/ unacceptable noise levels.