August 30, 2024

The Magstim Company Limited
Daniel Gregory
Principal Systems Engineer
Spring Gardens
Whitland
Carmarthenshire, SA34 0HR
United Kingdom

Re: K241518
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; QCI
Dated: May 29, 2024
Received: May 29, 2024

Dear Daniel Gregory:

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,

Vivek J. Pinto -S

Vivek Pinto, PhD
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)*

K241518

Device Name

Horizon® 3.0 TMS Therapy System (Horizon 3.0 Inspire);

Indications for Use *(Describe)*

Horizon 3.0 TMS Therapy System is indicated 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).

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

Prepared on: 2024-05-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	The Magstim Company Limited
Applicant Address	Spring Gardens Whitland Carmarthenshire SA34 0HR United Kingdom
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Applicant Contact	Mr. Daniel Gregory
Applicant Contact Email	daniel.gregory@magstim.com

Device Name

21 CFR 807.92(a)(2)

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

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K232235	Horizon 3.0 TMS Therapy System	OBP
K182853	Horizon TMS Therapy System	OBP

Device Description Summary

21 CFR 807.92(a)(4)

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 well as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

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 (Subject of this submission).
- Horizon 3.0 (Previously 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, including the subject Horizon 3.0 Inspire configuration, 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Horizon 3.0 TMS Therapy System is indicated 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).

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use for the subject device and the primary predicate device (K232235) are identical.

The reference predicate, K182853, where some of the subject device components have been re-used from was 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. The performance data within this submission, such as the applicating coil comparison to the primary predicate, demonstrate why these components do not raise any differing questions of safety or effectiveness when also used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

Technological Comparison

21 CFR 807.92(a)(6)

Introduction:
The Horizon® 3.0 TMS Therapy System is offered in three system configurations, the third of which is the subject of this submission:

Horizon 3.0, Horizon 3.0 with StimGuide Pro and Horizon 3.0 Inspire.

All system configurations, including the subject Horizon 3.0 Inspire configuration, feature the same core components and operating principles that drive the device. All three configurations, including the subject Horizon 3.0 Inspire configuration, 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, substantiated below.

Principles of Operation:
Horizon 3.0 Inspire is identical to the primary predicate device in terms of principles of operation. Horizon 3.0 Inspire is capable of delivering and provides the same recommended treatment protocols (OCD, rTMS and iTBS) as the primary predicate device.

The method for coil positioning is also identical to the primary predicate, with the Horizon 3.0 "Inspire" following the same principle of the statistical distance from the Motor Threshold (MT) Hotspot to the target area based on the chosen treatment (4cm from MT Hotspot, Dorsomedial Prefrontal Cortex, for OCD and 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 Inspire configuration remain identical to the primary predicate device configurations - Horizon 3.0 and Horizon 3.0 with StimGuide Pro.

Technological Characteristics:
The differences between Horizon 3.0 Inspire and the previously cleared device configurations from the primary predicate device are listed below. The intent of which is to reduce the cost and footprint for the end user whilst also providing an equivalent level of safety and effectiveness as the predicate device configurations. 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.

- The Horizon 3.0 Inspire Mainframe features a different "interface" panel on the rear of the mainframe. This is to support the connection to the Horizon 3.0 Inspire Touchscreen. The mainframe supplies power and communications via this interface. The fundamental principles of the Horizon 3.0 Inspire Mainframe remain identical to the predicate Horizon 3.0 Mainframe. The maximum output voltage, frequency, biphasic waveform, charging circuitry and protocol performance remain identical across all configurations. The only change was interface related to mount a UI touchscreen on the Mainframe.

- The Horizon 3.0 Interface Unit from the primary predicate device configurations is not required for the Horizon 3.0 Inspire configuration. It's functions have been integrated into other components. The PC has been moved from the Horizon 3.0 Interface Unit into the Horizon 3.0 Inspire Touchscreen, the EMG Amplifier has been moved into the Horizon 3.0 MEP Pod and some device control mechanisms previously performed via Horizon 3.0 Interface Unit now reside in the Horizon 3.0 Inspire Mainframe. In summary, the functions provided remain identical to the primary predicate and the technological changes were purely a reorganization of these functions to reduce the footprint of the system. Components such as the EMG Amplifier within the new Horizon 3.0 MEP Pod is the same module that is used on the primary predicate configurations.

- The Horizon 3.0 Inspire Touchscreen as described above now contains the PC that previously resided in the Horizon 3.0 Interface Unit. The technical specification is equivalent to the PC used in the Horizon 3.0 Interface Unit. Further, the Operating System and UI Software executing on the touchscreen are the same as that which executed on the Horizon 3.0 Interface Unit. The software was modified slightly to detect a Horizon 3.0 Inspire configuration and set up device communications accordingly. In summary, the functions provided remain identical to the primary predicate and the technological changes were purely a reorganization of these functions to reduce the footprint of the system.

- The Horizon 3.0 Inspire Mains Filter differs slightly from the standard Horizon 3.0 Mains Filter of the primary predicate device to ensure the Horizon 3.0 Inspire system as a whole remains compliant to IEC 60601-1 and IEC 60601-1-2 with respect to leakage currents, emissions and immunity.

- The treatment coil is different between the subject Horizon 3.0 Inspire compared to that used on the primary predicate device. The Horizon Air Film Coil is the designated treatment coil for the Horizon 3.0 Inspire configuration. The Horizon Air Film Coil has received prior clearance under K182853, K180907 and K171051 and was previously a predicate for introducing the E-z Cool Coil range to market. The coil magnetic and electric field output properties were compared to the primary predicate Horizon 3.0 E-z Cool Coil in accordance to the FDA's guidance "Class II Special Control Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS)" and special controls 21 C.F.R. § 882.5802 and 21 C.F.R. § 882.5805 to reaffirm it's suitability for treatment in accordance with the indications for use and were found to be substantially equivalent.

- The remaining minor technological changes are for the Cart, Coil Support and Accessory Cables. The Cart and Coil Support mechanism for the Horizon 3.0 Inspire configuration are the Magstim Trolley and Magstim Coil Stand respectively. Both components are of known provenance for supporting the weight of the system components and applicating coil as well as remaining stable during treatment delivery as these components have been previously cleared under K182853 and K180907. Most of the same cables have been re-used with the exception of the Mainframe communications and power USB leads. These cables have been tested in the full system testing as part of IEC 60601-1 type testing.

As can be seen from the summary above - technologically the Horizon 3.0 Inspire configuration which is the subject of this submission is very similar, and in some cases identical, to the primary predicate device configurations cleared under K232235. The technological changes can be considered more of a re-organizational exercise to provide a system of reduced footprint and cost to the end-user whilst still maintaining the same core principles, technology, safety and effectiveness of the primary predicate device.

This demonstrates all three configurations, including the subject Horizon 3.0 Inspire configuration, have identical intended use/ indications for use, common specifications, equivalent performance and equivalent composition.

All changes 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 10993-5, ISO 10993-10, 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 Inspire configuration such as Security Requirement, Threat Mitigation and Vulnerability testing was performed and documented in accordance with FDA guidance to demonstrate the Horizon 3.0 Inspire configuration is as secure as the primary predicate device and demonstrate the continued security of the Horizon® 3.0 TMS Therapy System family.

In conclusion - the Horizon® 3.0 TMS Therapy System with the addition of the Horizon 3.0 Inspire configuration and its technological differences from the previously cleared predicate device configurations do not raise any new or differing questions of safety or effectiveness and are substantially equivalent.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance testing of the Horizon® 3.0 TMS Therapy System with the addition of the Horizon 3.0 Inspire configuration demonstrates that the device performs as intended for the safe and effective treatment of MDD and as an adjunct for the treatment of OCD and is therefore substantially equivalent to the primary predicate device configurations - Horizon 3.0 and Horizon 3.0 with StimGuide Pro. 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 "Inspire" configuration 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 "Inspire" configuration 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 "Inspire" configuration 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 Thermal safety as the primary predicate device. Additional testing was performed to ensure that the Horizon Air Film 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. Changes made to introduce the Horizon 3.0 "Inspire" configuration have been verified for correctness and also do not negatively impact the Horizon 3.0/Horizon 3.0 with StimGuide Pro configurations.

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 coil 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 device 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 "Inspire" configuration with the Horizon Air Film Coil does 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 device introducing the Horizon 3.0 "Inspire" configuration is substantially equivalent to the primary predicate device cleared under K232235. The Horizon 3.0 "Inspire" offers an equivalent level of safety and effectiveness as the primary predicate Horizon 3.0 and Horizon 3.0 with StimGuide Pro configurations, whilst meeting its goal of offering an alternative system to meet organizational needs such as footprint and cost to ensure that as many patients as possible can gain access to safe and effective TMS Therapy Treatments.

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 Horizon 3.0 "Inspire" configuration utilized the same performance criteria as that used for the primary predicate device configurations. The test plan was composed of the same device specific criteria that was used to evaluate the primary predicate device configurations (Horizon 3.0 & Horizon 3.0 with StimGuide Pro) and therefore directly demonstrates a substantial equivalence of the subject Horizon® 3.0 TMS Therapy System introducing the Horizon 3.0 "Inspire" configuration.

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

Software Verification and Validation was performed on the subject Horizon 3.0 "Inspire" device configuration. The test procedure used to verify the subject Horizon 3.0 “Inspire” configuration was comprised of test cases used to verify the primary predicate device and its configurations: Horizon 3.0 and Horizon 3.0 with StimGuide Pro. This supports substantial equivalence as the software behavior is consistent and compatible across all configurations of the Horizon® 3.0 TMS Therapy System. The testing also included cybersecurity testing to ensure the subject Horizon 3.0 "Inspire" device configuration is as secure as the primary predicate device configurations.

Human Factors and Usability Engineering processes demonstrate the Horizon 3.0 “Inspire” configuration 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 and the introduction of the Horizon 3.0 “Inspire” configuration doesn’t raise any questions of safety or effectiveness with respect to usability and human factors.

Magnetic and Electric Field Testing demonstrated that the applicating coil of the subject device configuration - the Horizon Air Film Coil, is 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 both 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 both coils were virtually identical.

The Horizon Air Film Coil has been on the market since K143531 and is used by reference predicate device cleared under K182853. The Horizon Air Film Coil was previously used as the predicate for introducing the Horizon E-z Cool Coil range to market. The Horizon Air Film Coil has a known safety and effectiveness profile, especially for MDD treatments, and the nonclinical tests on the magnetic and electric fields of the Horizon Air Film Coil performed as part of this submission also demonstrates an equivalent level of safety and effectiveness for use as an adjunct for Obsessive Compulsive Disorder. As a result this demonstrates substantial equivalence between the subject Horizon 3.0 "Inspire" device configuration/applicating coil and the primary predicate device configurations/applicating coil.

Safety Feature Testing ensured all fault scenarios and safety features tested utilized similar (in the vast majority of cases, the same) procedures that were used to evaluate the primary predicate device, including compliance to IEC 60601-1. The testing provided within this submission demonstrates that there is substantial equivalence of safety features amongst all device configurations – importantly, including the subject Horizon 3.0 “Inspire” configuration.

Acoustic Testing in simulated use conditions (OCD Protocol at maximum machine output) for the subject Horizon 3.0 "Inspire" device configuration demonstrated equivalent acoustic properties to the primary predicate device. The values recorded for the subject device configuration fall below safe exposure limits demonstrating that Horizon 3.0 "Inspire" is as safe as the primary predicate device.

In conclusion - the subject Horizon® 3.0 TMS Therapy System with the addition of the Horizon 3.0 Inspire configuration is as safe and effective and is substantially equivalent to the primary predicate device cleared under K232235.