October 25, 2023

The Magstim Company Ltd.
Daniel Gregory
Principal Systems Engineer
Spring Gardens
Whitland, Carmarthenshire SA340HR
United Kingdom

Re: K232235
Trade/Device Name: 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
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: July 27, 2023
Received: July 27, 2023

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,

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

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)*
K232235

Device Name
Horizon 3.0 TMS Therapy System

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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K232235
Traditional 510(k) Summary
Magstim's Horizon® 3.0 TMS Therapy System

Prepared according to the requirements outlined in 21 CFR 807.92

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Magstim® Company Limited
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Contact Person: Daniel Gregory, Principal Systems Engineer (daniel.gregory@magstim.com)

Date Prepared: October 25, 2023

Trade Name of Device

Horizon® 3.0 TMS Therapy System

Common or Usual Name

Transcranial Magnetic Stimulation System for Neurological and Psychiatric Disorders and Conditions

Classification

21 C.F.R. § 882.5805, Class II, primary product code OBP
21 C.F.R. § 882.5802, Class II, subsequent product code QCI

Predicate Devices

Primary Predicate Device: Horizon 3.0® TMS Therapy System, The Magstim® Company Limited (K222171)

Product Code: 21 C.F.R. § 882.5805 OBP,

Subsequent Product Code: 21 C.F.R. § 882.5802 QCI

Device Description

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.

Horizon® 3.0 TMS Therapy System is an integrated system consisting of a combination of hardware, software, and accessories. Its technological characteristics are described in further detail below.

Intended Use & Indications for Use

The Horizon® 3.0 TMS Therapy System is intended to produce and deliver 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.

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).

Technological Characteristics

Horizon® 3.0 TMS Therapy Systems are offered in two system configurations: Horizon® 3.0 and Horizon® 3.0 with StimGuide Pro. These system configurations are comprised of the following physical components:

Table 1: System Configurations

Horizon® 3.0	Horizon® 3.0 with StimGuide Pro
1. Horizon® 3.0 Stimulator a. Horizon® 3.0 Mainframe; b. Horizon® 3.0 PSU (Power Supply Unit); c. Horizon® 3.0 Interface Unit; d. Horizon® 3.0 User Interface 2. Horizon® 3.0 Coil for MT Determination a. Horizon® MT Coil; 3. Horizon® 3.0 Coil for Treatment a. Horizon® 3.0 E-z Cool Coil 4. Horizon® 3.0 Cart and Coil Holder a. Horizon® 3.0 E-z Cart b. Horizon® 3.0 Coil Holder 5. Accessories a. Horizon® 3.0 Accessory Kit	1. Horizon® 3.0 Stimulator a. Horizon® 3.0 Mainframe; b. Horizon® 3.0 PSU (Power Supply Unit); c. Horizon® 3.0 Interface Unit; d. Horizon® 3.0 User Interface 2. Horizon® 3.0 Coil for MT Determination a. Horizon® MT Coil; 3. Horizon® 3.0 Coil for Treatment a. Horizon® 3.0 E-z Cool Coil (Nav) 4. Horizon® 3.0 Cart and Coil Holder a. Horizon® 3.0 E-z Cart; b. Horizon® 3.0 Coil Holder 5. Accessories a. Horizon® 3.0 Accessory Kit; b. StimGuide Pro Camera & Horizon® 3.0 Camera Stand c. StimGuide Pro Accessory Kit

The following technological changes are proposed for the Horizon® 3.0 TMS Therapy System which is the subject of this 510(k):

1. The Horizon 3.0 UI Software and StimGuide+ Navigation software have been combined onto a single screen to give a more integrated feel to the entire device. This has resulted in the minor rebranding of the StimGuide name to “StimGuide Pro”.
2. The StimGuide® Camera has been replaced, previously using an NDI Polaris Vicra Camera, with an OptiTrack V120:Duo Camera. The new camera has equivalent performance characteristics as the camera used on the predicate device. Testing of the tracking system with the new camera is described in the “Non-Clinical Testing” section below.
3. The EMG amplifier used within the predicate device – the StimGuide® Eego amplifier – has been replaced with an amplifier with equivalent performance characteristics, co-developed between Magstim and MentaLab GmbH. Testing of the EMG device is described in the “Non-Clinical Testing” section below.
4. Tracker Tools, which are sets of reflective spheres to help identify objects such as the Patient Head and Applicating Coil, have been modified to have slightly different arrangements to support the new camera system.
5. As a result of the Camera and EMG Amplifier changing, it was necessary to make some additional technological changes to support the integration of the above components:

a. The Horizon 3.0 UI Software and StimGuide+ Navigation software have been updated to integrate with the new Camera and EMG components. This includes the interpretation of the new Tracker Tools sphere placements to identify tracked rigid bodies. The updated StimGuide software has been rebranded as StimGuide Pro.
b. Modification to the pointer tool to allow remote interaction with the touchscreen to facilitate the landmarks registration process via Bluetooth, acting as a Human Interface Device (HID).
    i. Previously one hand would need to be placed on a landmark with the pointer tool and the other used to interact with the touchscreen. The remote function allows a user to use both hands for stabilizing the tool and register landmarks without needing to interact with the touchscreen.
    ii. The Bluetooth stack and chips used for communication were analyzed and not found to be vulnerable to exploits such as SweynTooth. This is documented further in **Section XVIII.I.**
c. The Camera Stand holding the camera has been slightly modified to support the new OptiTrack camera.
d. The Interface Unit which previously housed the StimGuide® Eego amplifier now houses the amplifier co-developed by Magstim and MentaLab GmbH.
e. Device labels and instructions for use updated to cover modified components.

6. This has resulted in a minor change in rebranding from 'StimGuide+' to 'StimGuide Pro'.
7. A Coil winding temperature interlock using solid state temperature sensors has been placed within the Horizon E-z Cool Coil 3.0 and Horizon E-z Cool Coil 3.0 (Nav) variant. This has been implemented due to the previous implementation of thermal fuses which may, under rare circumstances, activate as a result of mechanical shock when the coil is discharged. This addresses the issue whilst still providing the same level of safety as the predicate device. Performance testing has been documented in **Appendix 06.C.3.**

Please note that the MentaLab EMG Amplifier is manufactured as a component to be used in the manufacture and assembly of the updated Horizon 3.0 device.

Non-clinical Testing

Non-clinical testing was conducted to validate the performance of the subject Horizon® 3.0 TMS Therapy System and to ensure that the device performs as intended and meets the design specifications, consistent with the FDA's guidance "Class II Special Control Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS)."

As part of the update, Electrical Safety and Electromagnetic Compatibility ("EMC") testing were conducted on the subject device to demonstrate that the device remains compliant with IEC 60601-1 (Ed. 3.2), IEC 60601-1-2 (Ed. 4.1) and IEC 60601-1-8 (Ed. 2.2) following its modifications.

Human Factors Usability testing in accordance with IEC 62366-1 (Ed. 1.1) and AAMI/ANSI HE75:2009/(r)2018 was performed on the updated device with modifications to confirm that the subject device with its modifications continue to be safe and effective for the intended users, uses and use environments.

Biocompatibility testing from previous submissions (K222171) is leveraged for this 510(k) as the materials of the patient-contacting components of the system have not been modified and have been found to be compliant to the requirements of ISO 10993-1 (Ed. 5), ISO 10993-5 (Ed. 3) and ISO 10993-10 (Ed. 3). For completeness, the testing from the previous submission and a recent biological evaluation and gap analysis can be found in **Appendix 03.**

To evaluate the replacement of the Camera Tracking System, performance testing was performed to compare the modified system within the subject device to that used on the currently marketed predicate device. The performance testing included:

- Stress Testing to ensure maintained system performance and sampling rates under worst-case scenarios.

- Positional, Volumetric and Orientational Accuracy for tracked reflective spheres and rigid bodies.
- Evaluation that the new tracking system with a simulated Motor Threshold and Treatment procedure maintains the appropriate level of induced voltage when used to navigate to a treatment target from a Motor Threshold Hotspot.
- Direct Evaluation of Performance when used as a full system. The tracking system used with the currently marketed Horizon® 3.0 TMS Therapy System has previously been evaluated for performance against the manual method. This was repeated on the modified tracking system of the subject device and compared against that of the predicate device.
- Evaluation of EMG Amplifier performance characteristics compared to the predicate device.

A summary of the non-clinical testing performed on the subject Horizon® 3.0 TMS Therapy System is provided in **Table 2.**

A summary of the non-clinical performance testing used to evaluate the performance characteristics of the modified tracking system can be found in **Table 3.**

Table 2: Summary of Non-Clinical Testing

Test	Method	Results/ Comment
Electrical Safety Mechanical Safety Thermal Safety	ANSI/AAMI ES60601-1 (incl. AMD2:2021) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance; FDA Recognition Number: 19-46	A sample Horizon® 3.0 TMS Therapy System (specifically Horizon® 3.0 with StimGuide Pro) has been tested and found to be compliant to the requirements of ANSI/AAMI ES 60601-1 by independent test laboratory BSI Appliances, to demonstrate safety and effectiveness of the system following incorporation of new/ different characteristics as compared to the predicate device.
Electromagnetic Compatibility	IEC 60601-1-2 (2020) – Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -Requirements and tests; FDA recognition number: 19-36	A sample of the Horizon® 3.0 TMS Therapy System (specifically Horizon® 3.0 with StimGuide Pro) has been tested and found to be compliant to the requirements of IEC 60601-1-2 by independent test laboratory Eurofins Hursley, to demonstrate safety and effectiveness of the system following incorporation of new/ different characteristics as compared to the predicate device.
Alarm Systems	IEC 60601-1-8 (2020) – Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems; FDA Recognition Number: 5-131	A sample Horizon® 3.0 TMS Therapy System (specifically Horizon® 3.0 with StimGuide Pro) Horizon has been tested and found to be compliant to the requirements of IEC 60601-1-8 by independent test laboratory BSI Appliances, thus demonstrating the subject Horizon® 3.0 TMS Therapy System is substantially equivalent to the legally marketed predicate device.

Risk Management	ISO 14971 (2019) – Medical Devices – Application of risk management to medical devices; FDA Recognition Number: 5-125. AAMI TIR57 (2016 reaffirmed 2019) – Principles for medical device security – Risk Management; FDA Recognition Number: 13-83. AAMI TIR97:2019 – Principles for medical device security – Postmarket risk management for device manufacturers; FDA Recognition Number: 13-112	The potential risks of Horizon 3.0 have been identified and evaluated in compliance with ISO 14971, and the risks were determined to be acceptable, or have been addressed with risk control measures. In addition to ISO 14971:2019, AAMI TIR57:2016/(R)2019 and AAMI TIR97:2019 were also applied to evaluate and control cyber security risks associated with the Horizon 3.0 device and the risks were determined to be acceptable.
Software	IEC 62304 (2015) – Medical Device Software – Software life cycle processes; FDA Recognition Number: 13-79	The Software lifecycle process in accordance with IEC 62304, which includes verification and validation testing assures that the modified software performs as intended and in accordance with specifications.
Biocompatibility	ISO 10993-1 (2018) - Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process; FDA Recognition Number: 2-258 ISO 10993-5 (2009) - Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity; FDA Recognition Number: 2-245 ISO 10993-10 (2010) - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization; FDA Recognition Number: 2-174	Patient-contacting components of the Horizon® 3.0 TMS Therapy System include: • Enclosure of the Horizon® MT Coil; • Enclosure of the Horizon® Ez Cool Coil 3.0; • Enclosure of Horizon® Ez Cool Coil (Nav) 3.0, These components are unchanged from the predicate device. All these have limited contact duration with skin (surface contacting, less than 24-hour duration). Samples of these materials have been tested and found to be compliant to the requirements of ISO 10993-1, ISO 10993-5 and ISO 10993-10 by an independent test laboratory.

Cybersecurity Testing	AAMI TIR57 (2016 reaffirmed 2019) – Principles for medical device security – Risk Management; FDA Recognition Number: 13-83. AAMI TIR97:2019 – Principles for medical device security – Postmarket risk management for device manufacturers; FDA Recognition Number: 13-112	AAMI TIR57:2016/(R)2019 and AAMI TIR97:2019 were also applied to evaluate and control cyber security risks associated with the Horizon 3.0 device and the risks were determined to be acceptable. Penetration testing has been performed on the Azure Infrastructure and Patient Data Management items the system integrates with. Finally, the addition of the Bluetooth clicker tool was analyzed for Bluetooth vulnerabilities such as SweynTooth and was found not to be vulnerable to any known exploits. Off-the-shelf software packages used with the Horizon 3.0 devices have been updated to address any known vulnerabilities.
Human Factors Testing	AAMI/ANSI HE75 (2018) - Human Factors Engineering – Design of Medical Devices; FDA Recognition Number: 5-57 IEC 62366-1 (2020) - Medical Devices - Part 1: Application of Usability Engineering To Medical Devices; FDA Recognition Number: 5-129	Usability testing was performed on the subject Horizon® 3.0 TMS Therapy System. The Human Factors Engineering report verifies the subject Horizon® 3.0 TMS Therapy System, to be safe and effective for the intended users, uses, and use environments thus demonstrating the subject Horizon® 3.0 TMS Therapy System is substantially equivalent to the legally marketed predicate devices.

Non-clinical Testing – Tracking System:

As the updated Horizon® 3.0 TMS Therapy system replaces the tracking camera, EMG, updates the tracking tools and results in modifications to associated software systems – the following performance testing was performed to confirm that the changes in technological characteristics do not raise any new or differing questions of safety or effectiveness.

Expected results to evaluate equivalence were obtained from the tracking system used on the currently marketed Horizon® 3.0 TMS Therapy System (K222171):

Table 3: Summary of Non-Clinical Testing for Tracking System Update

Test	Method	Results/ Comment
Stress Testing – Sample Rate	System is set up to continuously sample using the camera while the host PC running the software is put under heavy load. **Expected Result:** Tracking remains stable under load to support sampling rates of 20Hz and 50Hz. 20Hz and 50Hz are chosen as this is the highest rate of	**Actual Results:** Maintains a constant sample rate above 50Hz. 50Hz chosen as that is the fastest rate of delivery out of cleared protocols. Under Abnormal PC Load: 52Hz min recorded.

Test	Method	Results/ Comment
	delivery for an FDA cleared protocol (OCD Protocol and iTBS Protocol).	Average Capture Rate in Normal Conditions: 120Hz/ **Equivalent to Predicate Device.**
Stress Testing – Data Storage	System is placed in a state for defining motor threshold and treatment delivery. Random points are then injected into the software to identify limits. **Expected Result:** 1000 rMT positions can be stored and 10,000 stimuli positions can be stored.	**Actual Results:** Supports recording of 1000 Simultaneous MT Locations for Motor Hotspot procedures and recording of up to 12,000 Stimuli which is sufficient for treatment (Maximum stimuli from FDA protocol is 3000) – **Equivalent to Predicate Device.**
Positional and Volumetric Accuracy – Camera Accuracy	At 25C temperature, A reflective marker is stepped through 1000 different positions (ground truths) with 30 samples taken at each position. **Expected Result:** <= 0.25mm Root Mean Squared (RMS) Positional Accuracy	**Actual Results:** 0.16mm RMS Positional Accuracy – **Equivalent to Predicate Device.**
Landmark Registration Accuracy (Rigid Body Testing)	At 25C temperature, A rigid body is defined using sets of reflective markers and are placed at known points (ground truths) where they are sampled. **Expected Result:** <= 1mm RMS Rigid-body Positional Accuracy	**Actual Results:** 0.45mm RMS Rigid-body Positional Accuracy – **Equivalent to Predicate Device.**
Orientational Accuracy	At 25C temperature, A rigid body is defined using sets of reflective markers and are moved along rotational axes by known amounts (ground truths) for Yaw, Pitch and Roll where the orientation of the body is then sampled. **Expected Result:** <= 5.5 degrees RMS Orientational Accuracy	**Actual Results:** 1.8 degrees RMS Orientational Accuracy **Equivalent to Predicate Device, provides an equivalent level of rotational accuracy.**
Treatment Delivery Performance on Phantom Head.	An MT workflow is performed in a simulated setting with a built-up system and tracker tools attached to the phantom head and coils. A stimuli is delivered at 50% machine output at a known position on the phantom head that is defined as the MT hotspot. The induced voltage was detected using a precisely positioned and secured pickup coil within the phantom head. The magnitude of this voltage was recorded. Subsequently, the new software and tracking system is used to navigate 5.5cm forward for MDD, 4cm forward for OCD in accordance with the principles of operation and a stimuli at the same power is delivered at the anticipated treatment target where there is another precisely positioned and secured pickup coil at the ideal location. **Expected Result:** Pickup coil should detect a reading of the same voltage	**Actual Results:** Over 20 samples (repeat of 10 tests for MDD and 10 tests for OCD) there was an average difference of 1.02% for MDD and 1.92% for OCD of the induced voltage when measured at the expected treatment target following the principles of operation. Resulting in a combined average difference of 1.47% from the voltage induced in a search coil at the MT location compared to when it is placed at the treatment location following the Navigation software. The treatment location was determined to be the location presented by Navigation software and when the software indicated it was in the position (green). **Equivalent to Predicate Device. When following the same principles of**

Test	Method	Results/ Comment
	induced at the MT hotspot and Treatment Target (+/- 5%).	**operation as the predicate device – the new tracking system results in equivalent output.**
Direct Accuracy Comparison to Manual Method and Predicate Device – Overall System Accuracy	Treatment targets are defined using the manual method as described in the Predicate Device operating manual. These points are then used as reference to compare to treatment targets generated using the tracking system of the Predicate Device and the tracking system of the Subject Device. This test takes into account all sources of error and is completed on a full system set-up. **Expected Result:** The mean difference between the manual method and the subject device navigation method is equivalent or better than the predicate device navigation method compared to the same manual method (< 4.0mm).	**Actual Results:** MDD Mean Difference to Manual Method (5.5cm forward from MT Hotspot): *1.51mm (Std. Dev 1.14mm)* OCD Mean Difference to Manual Method (4cm forward from MT Hotspot): *1.66mm (Std. Dev 0.76mm)* Compared to the results of the predicate device: Predicate – *3.0mm Mean Delta (Std. Dev 1.8mm)* Subject – *1.5mm (Std. Dev 1.1mm)* **Equivalent to Predicate Device – subject device offers better approximation/guidance to the treatment target in accordance with the principles of operation.**
EMG Performance.	Using a function generator, known waveforms are input into the EMG interface on the Horizon 3.0 device. A pulse is then delivered to trigger an EMG capture. The capture data collected by the amplifier and stored on the system is then compared to the known waveforms using the function generator. **Expected Result:** Timing Jitter between TMS Pulse and EMG Capture: < 5ms. Noise Level <5uV RMS. EMG Waveform Accuracy: error of < 10% in Amplitude and Time.	Timing Jitter Measured: Maximum of 3.25ms and mean of 1.68ms over samples. Noise Level Measured: 3.03uV RMS Waveform Accuracy Measured: Maximum Amplitude Error – 6.5%, Maximum Pulse Width Error – 3%, Maximum Frequency Error – 3.16% **Equivalent to Predicate Device. All measured values of the system are within tolerance.**

Further details on the testing can be found in the **Section XX – Performance Testing – Bench**

Clinical Testing

There is no clinical testing required to support this submission.

Substantial Equivalence

The Horizon® 3.0 TMS Therapy System – in both configurations, Horizon 3.0 and Horizon 3.0 with StimGuide Pro, which is the subject of this submission is substantially equivalent to the primary predicate device cleared under K222171. A full comparison table of characteristics can be found at the bottom of this summary.

The intended use and indications for use of the subject device when compared to the predicate device are identical, this is:

"*The 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).*"

The basic design of the subject Horizon® 3.0 TMS Therapy System is substantially equivalent to the design of the predicate device K222171, as both systems are based on applying transcranial magnetic stimulation by means of repetitive pulse trains at a predetermined frequency. All systems 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.

The technological characteristics of the device remain substantially equivalent to the predicate device. The camera tracking system and EMG amplifier components exhibit equivalent or better performance characteristics as described in **Table 3 and Table 4.** The modifications have been successfully tested to the requirements of IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-8 standards maintain the same level of Electrical, Mechanical and Thermal safety as the predicate device. The changes to the user interface have also been evaluated in accordance with IEC 62366-1 and ANSI/AAMI HE75 confirming no unacceptable use risks. Patient contacting parts remain identical to the predicate device, as well as their materials and formulation. As a result, it can be determined that none of the changes to the device raise any new or differing questions of safety and effectiveness.

The coil head geometry of the Horizon 3.0 MT Coil and E-z Cool Coil are identical to the predicate device. For this reason, the magnetic field characteristics of the system are identical to the predicate device, therefore equivalent safety and performance is assured. Consequently, no additional testing of the magnetic field characteristics of the system is necessary to meet the requirement of FDA's guidance document "Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems" in order to demonstrate safety and performance.

The principles of operation of the subject Horizon® 3.0 TMS Therapy System are equivalent to the primary predicate device. The method for determining Motor Threshold both with and without EMG and the coil positioning principle for treatment in both navigated and non-navigated device configurations for both MDD and OCD treatments remain unchanged compared to the predicate device. The recommended treatment protocols, the standard rTMS protocol, iTBS protocol, and OCD protocol are identical to those of the predicate devices.

Conclusion

The intended use and indications for use are identical between the subject Horizon® 3.0 TMS Therapy System and the primary predicate device cleared under K222171.

Although the technological characteristics of the subject device differ slightly following the update of the associated tracking camera and EMG device, non-clinical testing demonstrates that the subject device is as safe and effective compared to its primary predicate device, the Horizon® 3.0 TMS Therapy System (K222171).

Furthermore, despite the changes in technological characteristics - the principles of operation remain unchanged between the subject Horizon® 3.0 TMS Therapy System and its primary predicate, with the predicate recommending the options of using the Standard Treatment Protocol, iTBS Treatment Protocol and OCD Protocol. The method for MT Response Detection and the principle for Coil Position also remain the same as the primary predicates.

Thus, the information and data provided in this 510(k) premarket notification submission support a finding of substantial equivalence for the subject device, the updated Horizon® 3.0 TMS Therapy System, namely the Horizon 3.0 and Horizon 3.0 with StimGuide Pro.

Table 4: Substantial Equivalence Summary

Criteria	**Horizon 3.0 TMS Therapy System** Horizon 3.0 and Horizon 3.0 with StimGuide Pro (Subject of this submission)	**HORIZON 3.0 TMS Therapy System** Horizon 3.0 and Horizon 3.0 with StimGuide+ *(Primary Predicate)*	**Evaluation of Differences**
Manufacturer	Magstim Company Limited	Magstim Company Limited	
Device Name	Horizon 3.0 TMS Therapy System	Horizon 3.0 TMS Therapy System	
510(k) number(s)	K232235	K222171	
Device code	OBP, QCI	OBP, QCI	No Difference
Intended Use/ Indications for Use	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).	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).	No Difference
OCD Treatment Protocol			
Magnetic Field Intensity	100% of the MT	100% of the MT	No Difference
Stimulus Frequency	20 Hz	20 Hz	No Difference
Stimulus Train duration	2 sec	2 sec	No Difference
Inter-train interval	20 sec	20 sec	No Difference
Number of trains	50	50	No Difference
Magnetic Pulses per Session	2000	2000	No Difference
Treatment Session Duration	18.3 min	18.3 min	No Difference
Sessions/week	5	5	No Difference

Treatment Schedule	5 daily sessions for 5 weeks, 4 daily sessions for 1 week.	5 daily sessions for 5 weeks, 4 daily sessions for 1 week.	No Difference
Area of brain to be stimulated	Dorsomedial Prefrontal Cortex	Dorsomedial Prefrontal Cortex	No Difference
Standard Treatment Protocol)			
Magnetic Field Intensity	120% of the MT	120% of the MT	No Difference
Stimulus Frequency	10 Hz	10 Hz	No Difference
Stimulus Train duration	4 sec	4 sec	No Difference
Inter-train interval	11-26 sec	11-26 sec	No Difference
Number of trains	75	75	No Difference
Magnetic Pulses per Session	3000	3000	No Difference
Treatment Session Duration	18.8 min–37.5 min	18.8 min–37.5 min	No Difference
Sessions/week	5	5	No Difference
Treatment Schedule	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks	No Difference
Area of brain to be stimulated	Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex	No Difference
iTBS Treatment Protocol			
Stimulation Intensity	120% of the MT	120% of the MT	No Difference
Repetition Rate	50 Hz (5 pulses per sec)	50 Hz (5 pulses per sec)	No Difference
Train Duration	2 sec	2 sec	No Difference
Inter-train Interval	8 sec	8 sec	No Difference
Burst Pulses	3	3	No Difference
Bursts	200	200	No Difference

Inter Pulse interval	20 msec			20 msec			No Difference
Number of trains	20			20			No Difference
Number of Pulses per Session	600			600			No Difference
Treatment Session Duration	3.09 min			3.09 min			No Difference
Sessions/week	5			5			No Difference
Treatment Schedule	5 daily sessions for 6 weeks			5 daily sessions for 6 weeks			No Difference
Area of brain to be stimulated	Left Dorsolateral Prefrontal Cortex			Left Dorsolateral Prefrontal Cortex			No Difference
	Horizon® MT Remote Coil	Horizon® 3.0 E-z Cool Coil	Horizon® 3.0 E-z Cool Coil (Nav)	Horizon® MT Remote Coil	Horizon® 3.0 E-z Cool Coil	Horizon® 3.0 E-z Cool Coil (Nav)	
Waveform	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	No Difference
Core Material	Air	Air	Air	Air	Air	Air	No Difference
Pulse Width	330µs	340µs	340µs	330µs	340µs	340µs	No Difference
Amplitude in SMT units (Standard Motor Threshold)	0.28 - 1.9			0.28 - 1.9			No Difference
Frequency range (Hz) at 100%	1 – 20			1 - 20			No Difference
Pulse train duration range (sec)	0.1 – 600			0.1 - 600			No Difference
Inter-train interval range (sec)	1 – 540			1 - 540			No Difference
Maximum # of pulses per session (cumulative exposure)	60000			60000			No Difference

Maximum output amplitude (V/m) at a depth of 2cm below the coil surface	150 V/m	150 V/m	No Difference
Maximum magnetic field strength (T) at coil surface	1.0T	1.0T	No Difference
Maximum magnetic field strength (T) at a depth of 2cm	0.4T	0.4T	No Difference
Maximum magnetic field gradient (dB/dt) (kT/s) at coil surface	18 kT/s	18 kT/s	No Difference
Maximum magnetic field gradient (dB/dt) (kT/s) at a depth of 2cm	10 kT/s	10 kT/s	No Difference
Camera Tracking System and EMG Performance Characteristics			
Tracking System Accuracy (defined as accuracy of the Camera system)	0.16mm RMS	0.25mm RMS	Equivalent. Subject device camera tracking system exhibits equivalent performance characteristics.
Overall System Accuracy (defined as the accuracy of the overall system, accounting for tracking tools, rigid bodies and Landmark Registration)	< 4mm	< 10mm	Equivalent. Subject device camera tracking system exhibits equivalent performance characteristics.
EMG Performance	< 5ms Jitter (TMS Pulse to EMG Capture)	< 5ms Jitter (TMS Pulse to EMG Capture)	Equivalent. Subject device EMG Amplifier exhibits
	< 5uV Noise RMS	< 5uV Noise RMS	

	< 10% Error in Amplitude and Time		< 10% Error in Amplitude and Time		equivalent performance characteristics.
Coil Positioning and MT Determination Principle for OCD					
System Configuration	**Horizon 3.0**	**Horizon 3.0 with StimGuide Pro**	**Horizon 3.0**	**Horizon 3.0 with StimGuide+**	
Coil Position Principle for OCD	Indirect targeting of treatment target through measured distance and direction (4cm anterior) from Leg MT Hotspot. Measure derived from statistical distance of DMPFC/ACC from MT hotspot.	Indirect targeting of treatment target through measured distance and direction (4cm) from Leg MT Hotspot using stereotactic navigation. Measure derived from statistical distance of DMPFC/ACC from MT hotspot.	Indirect targeting of treatment target through measured distance and direction (4cm anterior) from Leg MT Hotspot. Measure derived from statistical distance of DMPFC/ACC from MT hotspot	Indirect targeting of treatment target through measured distance and direction (4cm) from Leg MT Hotspot using stereotactic navigation. Measure derived from statistical distance of DMPFC/ACC from MT hotspot.	Equivalent. The technological characteristics that support these principles (the StimGuide+ Camera, EMG Device and associated software) have been modified – but the principles remain identical between both the subject and primary predicate.
MT Response Principle for OCD	Visual qualitative monitoring for APB response		Visual qualitative monitoring for APB response		
Coil Positioning and MT Determination Principle for MDD					
Coil Position Principle for MDD	**Horizon 3.0**	**Horizon 3.0 with StimGuide Pro**	**Horizon 3.0**	**Horizon 3.0 with StimGuide+**	
Coil Position Principle for MDD	Indirect targeting of treatment target from MT Hotspot. Measure derived from statistical distance of DLPFC from MT hotspot.	Indirect targeting of treatment target through measured distance and direction (5.5cm) from MT Hotspot using stereotactic navigation. Measure derived from statistical distance of DLPFC from MT hotspot.	Indirect targeting of treatment target through measured distance and direction (5.5cm) from MT Hotspot. Measure derived from statistical distance of DLPFC from MT hotspot.	Indirect targeting of treatment target through measured distance and direction (5.5cm) from MT Hotspot using stereotactic navigation. Measure derived from statistical distance of DLPFC from MT hotspot.	Equivalent. The technological characteristics that support these principles (the StimGuide+ Camera, EMG Device and associated software) have been modified – but the principles remain identical between both the subject and

MT Response Principle for MDD	Visual qualitative monitoring for APB response	Option 1. EMG provides quantitative data based on which user defines MT. Option 2. Visual qualitative monitoring for APB response	Visual qualitative monitoring for APB response	Option 1. EMG provides quantitative data based on which user defines MT. Option 2. Visual qualitative monitoring for APB response	primary predicate.