March 3, 2019

Magstim Company Ltd.
Tom Campbell
Regulatory Affairs Manager
Spring Gardens
Whitland, Carmarthenshire
SA34 0HR, United Kingdom

Re: K183376
Trade/Device Name: HORIZON TMS Therapy System with Navigation
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP, HAW, IKN
Dated: February 28, 2019
Received: March 4, 2019

Dear Tom Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K183376

Device Name
HORIZON® TMS Therapy System with Navigation

Indications for Use *(Describe)*
HORIZON® 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.

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**
**Magstim's HORIZON® TMS Therapy System with Navigation**

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

Magstim Company Limited
Spring Gardens, Whitland, Carmarthenshire
SA34 0HR, United Kingdom

Phone: +44 (0) 1994 240798
Facsimile: +44 (0) 1994 240061

Contact Person: Tom Campbell

Date Prepared: April 3, 2019

## Name of Device

HORIZON® TMS Therapy System with Navigation

## Common or Usual Name

Repetitive Transcranial Magnetic Stimulation (rTMS) System

## Classification

Repetitive Transcranial Magnetic Stimulation (rTMS) System

21 C.F.R. § 882.5805, Class II, product code OBP

Additional Product Codes: HAW, IKN

## Predicate Devices

Mag Vita TMS Therapy System w/Theta Burst Stimulation, Tonica Elektronik A/S. (K173620) *(Primary Predicate)*
HORIZON® TMS Therapy System, The Magstim Company Limited. (K180907) *(Secondary Predicate)*
Nexstim Navigated Brain Therapy (NBT) System 2, Nexstim Plc. (K171902) *(Reference Predicate)*

## Device Description

The HORIZON® TMS Therapy System with Navigation (HORIZON®) 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.

The HORIZON® 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 antidepressant medication in the current episode. The HORIZON® 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® 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**

HORIZON® 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.

**Technological Characteristics**

HORIZON® is comprised of the following components:

1. HORIZON® TMS Therapy System
    a. HORIZON® User Interface;
    b. HORIZON® Mainframe;
    c. HORIZON® Power Supply;
    d. HORIZON® MT Remote Coil;
    e. HORIZON® E-z Cool Coil W/StimGuide Tracking Reference ('E-z Cool Coil (SG)');
    f. HORIZON® E-z Cart and Arm.
2. StimGuide
3. Accessories
    a. Interconnecting Cables;
    b. Footswitch;
    c. Pointer Tool;
    d. Head Reference.

The operator controls HORIZON® via the HORIZON® User Interface, using a graphic LCD panel with touchscreen technology. The operator instructions, given through the HORIZON® User Interface, direct the HORIZON® Mainframe in charging and discharging the device's high voltage pulse capacitor. The discharge is delivered to the patient via the stimulating coil. Motor threshold level can be determined using either the HORIZON® MT Remote Coil or the HORIZON® E-z Cool Coil (SG). Treatment is delivered to the treatment area via the HORIZON® E-z Cool Coil (SG), which is positioned above the treatment area. Positioning, and fixation, of the coil over the treatment area is accomplished using StimGuide and the HORIZON® E-z Arm. The HORIZON® Power Supply provides power to charge the high voltage pulse capacitor in the HORIZON® Mainframe.

Software documentation for a "moderate" level of concern has been provided.

**Non-Clinical Testing**

Electrical safety and electromagnetic compatibility ("EMC") testing were conducted on HORIZON® to demonstrate that the device is compliant with IEC 60601-1 (Ed. 3.1.) and IEC

60601-1-2 (Ed. 4.). Environmental testing and acoustic output measurements has been conducted during IEC 60601-1 (Ed. 3.1) testing to demonstrate safety and performance.

Biocompatibility evaluation has demonstrated that patient-contacting components of the HORIZON® TMS Therapy System meet the requirements of ISO 10993-1 (Ed. 4.) standards. In addition, acoustic output measurements have been conducted during IEC 60601-1 (Ed. 3.1) testing to demonstrate safety and performance.

The software verification and validation testing further demonstrated that the software performs as intended and in accordance with specifications, with exception of identified unresolved anomalies.

The potential risks of HORIZON® have been identified and evaluated in compliance with ISO14971, and the risks were determined to be acceptable, or have been addressed with risk control measures.

As required by FDA's Guidance Document titled "Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems", non-clinical magnetic field characteristic testing the HORIZON® TMS Therapy System was cleared by the FDA earlier in K180907. This testing has not been repeated as the magnetic field characteristics of the E-z Cool Coil (SG) are unchanged from the HORIZON® E-z Cool Coil.

**Substantial Equivalence**

HORIZON® is substantially equivalent to its predicate devices, the HORIZON® TMS Therapy System (K180907) and the Mag Vita TMS Therapy System w/Theta Burst Stimulation (K173620).

HORIZON® and the secondary predicate device (K180907) have identical intended use and indications for use, equivalent principles of operation, as well as the same key technological characteristics.

The technological difference between HORIZON® and that cleared earlier in K180907, includes the addition of StimGuide. StimGuide simplifies repeatable coil positioning using optical stereotactic navigation and introduces the option to use EMG for MT determination.

The design of HORIZON® is substantially equivalent to its predicate devices, as all 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.

Transcranial magnetic stimulation is enabled in HORIZON® and its predicate devices, as all have the same key system components, consisting of electromagnetic coils, a coil holding mechanism, a TMS stimulator and software.

The principles of operation of HORIZON® are similar to that cleared earlier in K180907, the differences being:

**Alternative method to determine and register treatment related landmarks**

The operation procedure for HORIZON® differs from that of the secondary predicate device (K180907) however the use of optical stereotactic coil positioning is supported by the reference predicate device, Nexstim Navigated Brain Therapy (NBT) System 2 (K171902). Combining optical stereotactic navigation with non-invasive TMS and simultaneous EMG, StimGuide is capable of locating areas of the brain capable of evoking muscle response when stimulated and locating the target area for depression therapy.

Non-clinical performance testing demonstrates that HORIZON® is both equivalent and as safe and effective as the secondary predicate device.

**Additional method to determine Motor Threshold (MT) using electromyography (EMG)**

The operation procedure for HORIZON® differs from that of the secondary predicate device (K180907) however is supported by the reference predicate device, Nexstim Navigated Brain Therapy (NBT) System 2 (K171902). Whereas, the secondary predicate device uses a visual observation of contractions of the Abductor Pollicis Brevis (APB) to determine resting Motor Threshold, HORIZON® introduces the option to use EMG in addition to visual observations of the APB response.

The clinical evidence to support the change to use EMG in addition to a visual APB response is supported by FDA clearance of reference predicate device, the Nexstim Navigated Brain Therapy (NBT) System 2 (K171902).

**Modification to the labelling to include a recommendation for an additional treatment protocol known as iTBS.**

This treatment protocol, is identical to the treatment protocol recommended by the primary predicate device, Mag Vita TMS Therapy System w/Theta Burst Stimulation (K173620).

Non-clinical performance testing has demonstrated that the change to the HORIZON® TMS Therapy System labelling to add a recommendation for an additional treatment protocol known as iTBS, raises no new issues of safety or effectiveness.

The similarities and minor differences between HORIZON®, HORIZON® TMS Therapy System *(Secondary Predicate),* Mag Vita TMS Therapy System w/Theta Burst Stimulation *(Primary Predicate) and* Nexstim Navigated Brain Therapy (NBT) System 2 *(Reference Predicate)* are described in **Table 1.**

HORIZON® meets the same electrical and mechanical safety standards (IEC 60601-1) and the same EMC standards (IEC 60601-1-2).

**Conclusions**

In summary, the intended use and indications for use for HORIZON® and the secondary predicate device, the HORIZON® TMS Therapy System (K180907) are identical.

Furthermore, HORIZON® shares the same key technological characteristics, as the secondary predicate device as both have the same key system components, consisting of electromagnetic coils, a coil holding mechanism, a TMS stimulator and software. The difference includes the addition of StimGuide for navigated coil positioning.

The principles of operation differ from that of the secondary predicate device (K180907). The differences include the addition of StimGuide which simplifies coil positioning using optical stereotactic navigation, the option to use EMG for MT determination and a modification to the labeling to include a recommendation for an additional treatment protocol known as iTBS. These changes are supported by the clearance of the primary predicate device (K173620) and the reference predicate device (K171902).

Non-clinical performance testing demonstrates that HORIZON® is both equivalent and as safe and effective as the secondary predicate device, the HORIZON® TMS Therapy System (K180907).

Thus, HORIZON® is considered substantially equivalent to its predicate devices.

**Table 1: Substantial Equivalence Summary**

| Criteria | **HORIZON® TMS Therapy System with Navigation** (Subject of this submission) | **Mag Vita TMS Therapy System w/Theta Burst Stimulation** (K173620) (*Primary Predicate*) | **HORIZON® TMS Therapy System** (K180907) *(Secondary Predicate)* | **Nexstim Navigated Brain Therapy (NBT) System 2** (K171902) (Reference *Predicate*) |
|---|---|---|---|---|
| **Manufacturer** | Magstim Company Limited | Tonica Elektronik A/S | Magstim Company Limited | Nexstim Plc |
| **Device Name** | HORIZON® TMS Therapy System with Navigation | Mag Vita TMS Therapy System w/Theta Burst Stimulation | HORIZON® TMS Therapy System | Nexstim Navigated Brain Therapy (NBT) System 2 |
| **Clearance date** | | 08/14/2018 | 08/03/2018 | 11/10/2018 |
| **510(k) number** | | K173620 | K180907 | K171902 |
| **Device code** | OBP | OBP | OBP | OBP, GWF, HAW, IKN |
| **Intended Use/ Indications for Use** | The HORIZON® 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. | The Mag Vita TMS Therapy System w/Theta Burst Stimulation is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode. | The HORIZON® 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. | Nexstim Navigated Brain Therapy (NBT) System 2 is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode. |
| **Standard Treatment Protocol** | | | | |
| **Magnetic Field Intensity** | 120% of the MT | N/A | 120% of the MT | 120% of the MT |
| **Stimulus Frequency** | 10 Hz | N/A | 10 Hz | 10 Hz |
| **Stimulus Train duration** | 4 sec | N/A | 4 sec | 4 sec |
| **Inter-train interval** | 11-26 sec | N/A | 11-26 sec | 26 sec |
| **Number of trains** | 75 | N/A | 75 | 75 |

| | | | | |
|---|---|---|---|---|
| **Magnetic Pulses per Session** | 3000 | N/A | 3000 | 3000 |
| **Treatment Session Duration** | 18.8 min–37.5 min | N/A | 18.8 min–37.5 min | 37.5 min |
| **Sessions/week** | 5 | N/A | 5 | 5 |
| **Treatment Schedule** | 5 daily sessions for 6 weeks | N/A | 5 daily sessions for 6 weeks | 5 daily sessions for 6 weeks |
| **Area of brain to be stimulated** | Left Dorsolateral Prefrontal Cortex | N/A | Left Dorsolateral Prefrontal Cortex | Left Dorsolateral Prefrontal Cortex |
| **iTBS Treatment Protocol** | | | | |
| **Stimulation Intensity** | 120% of the MT | 120% of the MT | N/A | N/A |
| **Repetition Rate** | 50 Hz (5 pulses per sec) | 50 Hz (5 pulses per sec) | N/A | N/A |
| **Train Duration** | 2 sec | 2 sec | N/A | N/A |
| **Inter-train Interval** | 8 sec | 8 sec | N/A | N/A |
| **Burst Pulses** | 3 | 3 | N/A | N/A |
| **Bursts** | 200 | 200 | N/A | N/A |
| **Inter Pulse interval** | 20 msec | 20 msec | N/A | N/A |
| **Number of trains** | 20 | 20 | N/A | N/A |
| **Number of Pulses per Session** | 600 | 600 | N/A | N/A |
| **Treatment Session Duration** | 3.09 min | 3.09 min | N/A | N/A |
| **Sessions/week** | 5 | 5 | N/A | N/A |
| **Treatment Schedule** | 5 daily sessions for 6 weeks | 5 daily sessions for 6 weeks | N/A | N/A |

| **Area of brain to be stimulated** | Left Dorsolateral Prefrontal Cortex | | Left Dorsolateral Prefrontal Cortex | N/A | | | N/A |
|---|---|---|---|---|---|---|---|
| | HORIZON® MT Remote Coil | HORIZON® E-z Cool Coil (SG) | Cool-B70 Coil | HORIZON® MT Remote Coil | HORIZON® E-z Cool Coil | HORIZON® AFC | Nexstim Stimulation Coil |
| **Waveform** | Biphasic | Biphasic | Biphasic | Biphasic | Biphasic | Biphasic | Biphasic |
| **Core Material** | Air | Air | Air | Air | Air | Air | Air |
| **Shape** | Figure-of-eight | Figure-of-eight | Figure-of-eight | Figure-of-eight | Figure-of-eight | Figure-of-eight | Figure-of-eight |
| **Coil Winding Configuration**<br>*Inner Diameter (ID)*<br>*Outer Diameter (OD)*<br>*Winding Height (H)*<br>*Number of Windings (NW)* | ID: 55mm<br>OD: 92mm<br>H: 6mm<br>NW: 2x9 | ID: 37.5mm<br>OD: 97mm<br>H: 11mm<br>NW: 2x(3x23) | ID: 23mm<br>OD: 96mm<br>H: 12mm<br>NW: 2x11 | ID: 55mm<br>OD: 92mm<br>H: 6mm<br>NW: 2x9 | ID: 37.5mm<br>OD: 97mm<br>H: 11mm<br>NW: 2x(3x23) | ID: 43mm<br>OD: 92mm<br>H: 11mm<br>NW: 2x(3x19) | ID: unknown<br>OD: unknown<br>H: unknown<br>NW: 2x10 |
| **Pulse Width** | 330µs | 340µs | 280µs | 330µs | 340µs | 300µs | 230µs |
| **Amplitude in SMT units**<br>(Standard Motor Threshold) | 0.28 - 1.9 | | 0 – 1.7 | 0.28 - 1.9 | | | 0 - 2.5 |
| **Frequency range (Hz) at 100%** | 1 - 20 | | 0.1 - 30 | 1 - 20 | | | 0.1-50 Hz |
| **Coil Position Principle** | Indirect targeting of treatment target through measured distance and direction (5.5cm) from MT Hotspot using optical 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. Measure derived from statistical distance of DLPFC from MT hotspot. | | | Individual patient direct targeting of anatomical treatment location (DLPFC).<br>Placing of E-field maximum location on 3D model built from patients individual MRi. |

| | | | | |
|---|---|---|---|---|
| **MT Response Detection** | Option 1. EMG provides quantitative data based on which user defines MT.<br>Option 2. Visual qualitative monitoring for APB response | Visual qualitative monitoring for APB response | Visual qualitative monitoring for APB response | EMG provides quantitative data based on which user defines MT. |