March 15, 2019

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

Re: K182853
Trade/Device Name: HORIZON TMS Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: February 5, 2019
Received: February 11, 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)*
K182853

Device Name
HORIZON TMS Therapy System

Indications for Use *(Describe)*
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.

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

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

Magstim Company Limited
Spring Gardens, Whitland, Carmarthenshire
SA34 OHR, United Kingdom

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

Contact Person: Tom Campbell

Date Prepared: March 15, 2019

Name of Device

HORIZON® TMS Therapy System

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

Predicate Device

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)*

Device Description

The HORIZON® 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.

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

Technological Characteristics

The HORIZON® TMS Therapy System is comprised of the following components:

1. HORIZON® Stimulator
    a. HORIZON® User Interface;
    b. HORIZON® Mainframe;
    c. HORIZON® Power Supply;
    d. Accessory Cables;
    e. Accessory Footswitch.
2. Coil for MT Determination
    a. HORIZON® MT Remote Coil.
3. Coil(s) for Treatment
    a. HORIZON® AFC;
    b. HORIZON® E-z Cool Coil.
4. Accessory Cart(s) and Coil Holding Mechanism(s)
    a. Magstim® Trolley;
    b. Magstim® Coil Stand(s);
    c. HORIZON® E-z Cart;
    d. HORIZON® E-z Arm.
5. Accessory Marking Apparatus
    a. TMS Patient Caps.

The operator controls the HORIZON® TMS Therapy System 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 discharge capacitor. The discharge is delivered to the patient via the stimulating coil. Motor threshold level can be determined using the HORIZON® MT Remote Coil. Treatment is delivered to the treatment area via either the HORIZON® AFC or the HORIZON® E-z Cool Coil, which is positioned above the treatment area. Positioning, and fixation, of the coil over the treatment area is accomplished using the Coil Holding Mechanism(s). The HORIZON® Power Supply provides power to charge the high voltage capacitor in the HORIZON® Mainframe.

Non-Clinical Performance Testing

The non-clinical performance testing of the HORIZON® TMS Therapy System including electrical safety, electromagnetic compatibility, biocompatibility, human factors and magnetic field characteristics has been tested as required and cleared by the FDA earlier in K180907.

Additional verification testing has demonstrated that the intensity of the individual stimuli in iTBS is equal and kept constant throughout the delivery of the full treatment. As stated by the primary predicate device (K173620), the clinical performance of iTBS is dependent on the stimuli being delivered at equal intensity, to ensure that a constant dose of stimuli is delivered during treatment.

This demonstrates that the HORIZON® TMS Therapy System is safe and effective for use in treatment of Major Depressive Disorder.

Substantial Equivalence

The HORIZON® TMS Therapy System 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).

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

The key technological characteristics including basic design, mechanism of action, specifications are also identical for both the HORIZON® TMS Therapy System and the secondary predicate device (K180907).

The principles of operation of the HORIZON® TMS Therapy System is equivalent to the secondary predicate device, the HORIZON® TMS Therapy System (K180907). The only change to the HORIZON® TMS Therapy System is a 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, the Mag Vita TMS Therapy System w/Theta Burst Stimulation (K173620). The design of the HORIZON® TMS Therapy System is unchanged from that previously cleared under K180907.

Transcranial magnetic stimulation is enabled in the HORIZON® TMS Therapy System and in the predicate devices, as all have the same key system components, consisting of electromagnetic coils, a coil holding mechanism, a TMS stimulator and software. The operation procedure consisting of system setup, patient preparation, determination of patients' motor threshold, coil position, and administration of treatment at pre-defined treatment stimulation parameters is unchanged in the HORIZON® TMS Therapy System to that cleared earlier in (K180907).

The basic software capabilities related to treatment administration are the same as the secondary predicate (K180907)

The HORIZON® TMS Therapy System meets the same electrical and mechanical safety standards (IEC 60601-1) and the same EMC standards (EN 60601-1-2).

The similarities and minor differences between the HORIZON® TMS Therapy System, the Mag Vita TMS Therapy System w/Theta Burst Stimulation (K173620) *(Primary Predicate) and* the HORIZON® TMS Therapy System (K180907) *(Secondary Predicate)* are described in **Table 1.**

Conclusions

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

Furthermore, the key technological characteristics including basic design, mechanism of action, specifications are also identical for both the HORIZON® TMS Therapy System and the secondary predicate device (K180907).

The principles of operation, including the method for determining coil position, the treatment procedure and the relevant protocol parameters are substantially equivalent to the predicate devices.

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. Furthermore, the intended use, as described in the labeling, has not changed as a result of this modification.

Thus, the HORIZON® TMS Therapy System is considered to be substantially equivalent.

Table 1: Substantial Equivalence Summary

Criteria	**HORIZON® TMS Therapy System** (Subject of this submission)	**Mag Vita TMS Therapy System w/Theta Burst Stimulation** (K173620) (Primary *Predicate*)	**HORIZON® TMS Therapy System** (K180907) *(Secondary Predicate)*
Manufacturer	Magstim Company Limited	Tonica Elektronik A/S	Magstim Company Limited
Device Name	HORIZON® TMS Therapy System	Mag Vita TMS Therapy System w/Theta Burst Stimulation	HORIZON® TMS Therapy System
Clearance date		08/14/2018	08/03/2018
510(k) number		K173620	K180907
Device code	OBP	OBP	OBP
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.
Standard Treatment Protocol			
Magnetic Field Intensity	120% of the MT	-	120% of the MT
Stimulus Frequency	10 Hz	-	10 Hz
Stimulus Train duration	4 sec	-	4 sec
Inter-train interval	11-26 sec	-	11-26 sec
Number of trains	75	-	75
Magnetic Pulses per Session	3000	-	3000

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

	HORIZON® MT Remote Coil	HORIZON® E-z Cool Coil	HORIZON® AFC	Cool-B70 Coil	HORIZON® MT Remote Coil	HORIZON® E-z Cool Coil	HORIZON® AFC
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 *Inner Diameter (ID)* *Outer Diameter (OD)* *Winding Height (H)* *Number of Windings (NW)*	ID: 55mm OD: 92mm H: 6mm NW: 2x9	ID: 37.5mm OD: 97mm H: 11mm NW: 2x(3x23)	ID: 43mm OD: 92mm H: 11mm NW: 2x(3x19)	ID: 23mm OD: 96mm H: 12mm NW: 2x11	ID: 55mm OD: 92mm H: 6mm NW: 2x9	ID: 37.5mm OD: 97mm H: 11mm NW: 2x(3x23)	ID: 43mm OD: 92mm H: 11mm NW: 2x(3x19)
Pulse Width	330µs	340µs	300µs	280µs	330µs	340µs	300µs
Amplitude in SMT units (Standard Motor Threshold)	0.28 - 1.9			0 – 1.7	0.28 - 1.9		
Frequency range (Hz) at 100%	1 - 20			0.1 - 30	1 - 20		