DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 13, 2017

Magstim Company Ltd.
Tom Campbell
Regulatory Affairs Officer
Spring Gardens
Whitland, SA34 0HR Gb

Re: K171051/S002
Trade/Device Name: HORIZON Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: May 23, 2017
Received: August 10, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

William J. Heetderks -S
2017.09.13 08:48:43 -04'00'

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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

Device Name

HORIZON™ Therapy System

Indications for Use *(Describe)*

The HORIZON™ 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY
Magstim's HORIZON™ 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: August 29, 2017

Name of Device

HORIZON™ 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 Devices

Magstim Rapid² Therapy System, The Magstim Company Limited. (K143531 and K162935)

Device Description

The HORIZON™ 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™ 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™ 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™ 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™ 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™ Therapy System is comprised of five principal components. These include:

1) HORIZON™ User Interface;
2) HORIZON™ Mainframe;
3) HORIZON™ Power supply;
4) HORIZON™ Air Film Coil;
5) HORIZON™ MT Remote Coil;
6) Accessory HORIZON™ Cart;
7) Accessory Coil Holding Mechanism;
8) Accessory Footswitch;
9) Accessory Cables; and
10) Accessory TMS Patient Caps.

The operator controls the HORIZON™ 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 the HORIZON™ Air Film Coil, which is positioned above the treatment area. Positioning, and fixation, of the coil over the treatment area is accomplished using an Accessory Coil Holding Mechanism. The HORIZON™ Power Supply provides power to charge the high voltage 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 was conducted on the system to demonstrate that the device is compliant with IEC 60601-1 (Ed. 3.1.) and IEC 60601-1-2 (2007). Environmental testing also demonstrated compliance with IEC 60601-1. The biocompatibility evaluation demonstrated that both coils meet ISO 10993-1 (2009) 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. The potential risks of HORIZON™ Therapy System 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 demonstrated in **Section XIII**, **Section XIV** and **Appendix 03** the coil head geometry of both the HORIZON™ Air Film Coil and HORIZON™ MT Remote Coil are identical to the predicate devices, the Air Film Coil and D70mm MT Remote Coil, cleared under K143531 and K162935. 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.

In summary, performance testing demonstrates that the HORIZON™ Therapy System is as safe and effective as the predicate.

Substantial Equivalence

The HORIZON™ Therapy System has the same intended use and indications for use, the same principles of operation, as well as the same key technological characteristics as the predicate device.

The design of the HORIZON™ Therapy System is substantially equivalent to the design of the predicate, as both systems are based on applying transcranial magnetic stimulation by means of repetitive pulse trains at a predetermined frequency. Both 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 modifications from the predicate device include increased thermal performance and reliability of the mainframe and power supply and a new coil to mainframe connector to improve reliability and usability.

Transcranial magnetic stimulation is enabled in the HORIZON™ Therapy System and in the Rapid² Therapy System, as both have the same key system components, consisting of electromagnetic coils, a coil holding mechanism, a TMS stimulator and software. The operation procedure is the same in both the HORIZON™ Therapy System and the Rapid² Therapy System consisting of system setup, patient preparation, determination of patients' motor threshold, coil position, and administration of treatment at pre-defined treatment stimulation parameters. The similarities and minor differences between the HORIZON™ Therapy System and the Rapid² Therapy System are described in **Table 1.**

Table 1: Substantial Equivalence Summary

Criteria	HORIZON™ Therapy System (Subject of this submission)	Rapid² Therapy System
Manufacturer	Magstim Company Limited	Magstim Company Limited
Device Name	HORIZON™ Therapy System	Rapid² Therapy System
Clearance date		2017/03/10
510(k) number		K143531 and K162935
Device code	OBP	OBP
Intended Use/ Indications for Use	The HORIZON™ 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 Rapid² 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.
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	26 sec	26 sec
Number of trains	75	75
Magnetic Pulses per Session	3000	3000
Treatment Session Duration	37.5 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
MT Determination Coil Parameters		
	HORIZON™ MT Remote Coil Part #: 4990-00	D70 MT Remote Coil Part #: 4949-00
Waveform	Biphasic	Biphasic
Configuration	Figure 8	Figure 8
Core Material	Air	Air
Coil Winding Parameters	Flat spiral winding 9 turns/wing 1.75 × 6mm wire Magstim Part #: 3302-01	Flat spiral winding 9 turns/wing 1.75 × 6mm wire Magstim Part #: 3302-01

Criteria	**HORIZON™ Therapy System** (Subject of this submission)	**Rapid² Therapy System**
Inductance (nominal)	15µH	15µH
Pulse Width	330µs	330µs
Coil Connector	Harting Han-Eco Connector	Trident Ringlock Circular Connector
Treatment Delivery Coil Parameters		
	HORIZON™ Air Film Coil Part #: 4980-00	Air Film Coil Part #: 3910-00
Waveform	Biphasic	Biphasic
Configuration	Figure 8	Figure 8
Core Material	Air	Air
Coil Winding Parameters	Flat spiral winding 19 turns/wing, 3 lyrs 1.0 × 3.5mm wire Magstim Part #: 0056-01	Flat spiral winding 19 turns/wing, 3 lyrs 1.0 × 3.5mm wire Magstim Part #: 0056-01
Inductance (nominal)	12µH	12µH
Pulse Width	300µs	300µs
Coil Connector	Harting Han-Eco Connector	Trident Ringlock Circular Connector
Stimulator Output Parameters		
Amplitude in SMT units (Standard Motor Threshold)	0.28 - 1.9	0.28 - 1.9
Frequency range (Hz) at 100%	1 - 20	1 - 11
Pulse train duration range (sec)	0.1 - 600	0.1 - 600
Inter-train interval range (sec)	1 - 540	1 - 540
Maximum trains per session	1 - 999	1 - 999
Maximum # of pulses per session (cumulative exposure)	6000	65000
Method for determining Motor Threshold	• Place device over the left motor region • Determine patient sensitivity • Adjust coil position to identify region of maximal response in contra-lateral hand. • Reduce output amplitude to determine threshold of stimulation	• Place device over the left motor region • Determine patient sensitivity • Adjust coil position to identify region of maximal response in contra-lateral hand. • Reduce output amplitude to determine threshold of stimulation
Method for determining coil treatment position	5.5cm anterior to motor hotspot	5.5cm anterior to motor hotspot

Criteria	HORIZON™ Therapy System (Subject of this submission)	Rapid² Therapy System
Maximum output amplitude (V/m) at a depth of 2cm below the coil surface	150 V/m	150 V/m
Maximum magnetic field strength (T) at coil surface	1.0T	1.0T
Maximum magnetic field strength (T) at a depth of 2cm	0.4T	0.4T
Maximum magnetic field gradient (dB/dt) (kT/s) at coil surface	18 kT/s	18 kT/s
Maximum magnetic field gradient (dB/dt) (kT/s) at a depth of 2cm	10 kT/s	10 kT/s
Magnetic field strength gradient ratio	1.8	1.8

The basic software capabilities related to treatment administration are the same as the predicate device.

The HORIZON™ Therapy System 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 the HORIZON™ Therapy System and the Rapid² Therapy System are identical. Furthermore, the key technological characteristics and principles of operation, including basic design, mechanism of action, specifications and treatment procedure are the same. Non-clinical test data demonstrates that the HORIZON™ Therapy System is as safe and effective as the predicate.

Thus, the HORIZON™ Therapy System is substantially equivalent to the Rapid² Therapy System.