August 3, 2018

Magstim Company Ltd.
Tom Campbell
Regulatory Affairs Manager
Spring Gardens
Whitland, Camarthenshire
Wales, UK SA34 0HR

Re: K180907
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: July 2, 2018
Received: July 5, 2018

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

Digitally signed by Pamela D. Scott -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000062976, cn=Pamela D. Scott -S
Date: 2018.08.03 18:58:54 -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 below.

510(k) Number *(if known)*
K180907

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 0HR, United Kingdom

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

Contact Person: Tom Campbell

Date Prepared: July 30, 2018

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 Devices

HORIZON® Therapy System, The Magstim Company Limited. (K171051) *(Primary Predicate)*
NeuroStar TMS Therapy System, Neuronetics, Inc. (K160703) *(Secondary Predicate)*
Neurosoft TMS, TeleEMG, LLC. (K173441) *(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.

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 EN 60601-1-2 (2007). Environmental testing also demonstrated compliance with IEC 60601-1.

EN 60601-1-2 (2007) is not an FDA recognized standard and hence a justification of its equivalence to the appropriate FDA recognized standard for its acceptance has been provided.

The biocompatibility evaluation demonstrated that the stimulation 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® TMS 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 required by FDA's Guidance Document titled "Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems", non-clinical testing of the HORIZON® TMS Therapy System included testing of the magnetic field characteristics of the system. The results of this testing demonstrate that the magnetic field characteristics of the HORIZON® TMS Therapy System is substantially equivalent to the primary predicate device, the HORIZON® Therapy System (K171051).

Substantial Equivalence

The HORIZON® TMS Therapy System is substantially equivalent to the primary predicate device, the HORIZON® Therapy System (K171051).

The HORIZON® TMS Therapy System and the primary predicate device (K171051) have identical intended use and indications for use, equivalent principles of operation, as well as the same key technological characteristics.

The technological difference between the HORIZON® TMS Therapy System and the HORIZON® Therapy System (K171051), includes the addition of the HORIZON® E-z Cool Coil, HORIZON® E-z Cart and HORIZON® E-z Arm. These changes raise no new issues of safety or effectiveness. Performance data demonstrates that the HORIZON® TMS Therapy System is as safe and effective as the primary predicate device.

The design of the HORIZON® TMS Therapy System is substantially equivalent to the design of the primary predicate device (K171051), 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 principles of operation of the HORIZON® TMS Therapy System is equivalent to the HORIZON® Therapy System (K171051). The modification to the device allows a range of inter-train intervals from 11 to 26 seconds, rather than the fixed 26 second duration, which allows a reduction in treatment time from 37.5 minutes to a minimum of 18.8 minutes. The change to this output stimulation parameter is identical to the secondary predicate device, the NeuroStar TMS Therapy System (K160703).

Transcranial magnetic stimulation is enabled in the HORIZON® TMS Therapy System and in the HORIZON® Therapy System (K171051), 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® TMS Therapy System and the HORIZON® Therapy System (K171051), consisting of system setup, patient preparation, determination of patients' motor threshold, coil position, and administration of treatment at pre-defined treatment stimulation parameters.

The basic software capabilities related to treatment administration are the same as the primary predicate, the HORIZON® Therapy System (K171051). A notable difference is that the arbitrary upper limit imposed by software for the maximum number of pulses per session (cumulative exposure) has been increased from 6000 to 60,000 in the HORIZON® TMS Therapy System. This is supported by TeleEMG, LLC's Neurosoft TMS (K173441) that is capable of delivering a maximum of 72,000.

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 HORIZON® Therapy System *(Primary Predicate)*, the NeuroStar TMS Therapy System *(Secondary Predicate)* and the Neurosoft TMS *(Secondary Predicate)* are described in **Table 1.**

Conclusions

In summary, the intended use and indications for use for the HORIZON® TMS Therapy System and primary predicate device, The HORIZON® Therapy System (K171051) are identical.

Furthermore, the key technological characteristics and principles of operation, including basic design, mechanism of action, specifications and treatment procedure are substantially equivalent.

Non-clinical test data demonstrates that the HORIZON® TMS Therapy System is as safe and effective as the HORIZON® Therapy System (K171051).

Thus, the HORIZON® TMS Therapy System is considered substantially equivalent to the primary predicate device, the HORIZON® Therapy System (K171051).

Table 1: Substantial Equivalence Summary

Criteria	**HORIZON® TMS Therapy System** (Subject of this submission)	**HORIZON® Therapy System** (K171051) *(Primary Predicate)*	**NeuroStar TMS Therapy System** (K160703) *(Secondary Predicate)*	**Neurosoft TMS** (K173441) (*Secondary Predicate*)
Manufacturer	Magstim Company Limited	Magstim Company Limited	Neuronetics Inc.	TeleEMG, LLC
Device Name	HORIZON® Therapy System	HORIZON® Therapy System	NeuroStar TMS Therapy System	Neurosoft TMS
Clearance date		09/13/2017	06/10/2016	12/13/2017
510(k) number		K171051	K160703	K173441
Device code	OBP	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 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 NeuroStar 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 Neurosoft TMS 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.
Magnetic Field Intensity	120% of the MT	120% of the MT	120% of the MT	120% of the MT
Stimulus Frequency	10 Hz	10 Hz	10 Hz	10 Hz
Stimulus Train duration	4 sec	4 sec	4 sec	4 sec
Inter-train interval	11-26 sec	26 sec	11-26 sec	11-26 sec
Number of trains	75	75	75	75
Magnetic Pulses per Session	3000	3000	3000	3000
Treatment Session Duration	18.8 min–37.5 min	37.5 min	18.8 min – 37.5 min	18.8 min–37.5 min

Sessions/week	5			5		5	5
Treatment Schedule	5 daily sessions for 6 weeks			5 daily sessions for 6 weeks		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		Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex
	HORIZON® MT Remote Coil	HORIZON® E-z Cool Coil	HORIZON® AFC	HORIZON® MT Remote Coil	HORIZON® AFC	NeuroStar Stimulating Coil	FEC-02-100-C, AFEC-02-100-C FEC-02-100 (optional), AFEC-02-100 (optional)
Waveform	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Core Material	Air	Air	Air	Air	Air	Ferromagnetic core	Air
Pulse Width	330µs	340µs	300µs	330µs	300µs	185µs	280µs
Amplitude in SMT units (Standard Motor Threshold)	0.28 - 1.9			0.28 - 1.9		0.22 - 1.6	FEC-02-100-C 0-1.89 AFEC-02-100-C 0-2.38 FEC-02-100 0-1.92 AFEC-02-100 0-2.33
Frequency range (Hz) at 100%	1 - 20			1 - 20		0.1-30	0.1-30 (stand-alone) 0.1-100 (with PC)
Pulse train duration range (sec)	0.1 - 600			0.1 - 600		1-20	0.5 - 100
Inter-train interval range (sec)	1 - 540			1 - 540		10-60	0 - 300
Maximum # of pulses per session (cumulative exposure)	60000			6000		5000	72000 (Stand-alone) = 2400 s [max session] *30Hz 240000 (with PC) = 2400 s [max session] * 100Hz
Maximum output amplitude (V/m) at a depth of 2cm below the coil surface	150 V/m			150 V/m		135V/m nominal	Not disclosed by Manufacturer