DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 8, 2015

Magstim Company Limited
C/O Janice Hogan
Partner, Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, PA 19103

Re: K143531
Trade/Device Name: Rapid^2 Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulation system
Regulatory Class: Class II
Product Code: OPB
Dated: April 10, 2015
Received: April 10, 2015

Dear Ms. Hogan:

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 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" (21CFR 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 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 yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
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

Rapid^2 Therapy System

Indications for Use *(Describe)*

The Rapid^2 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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
Magstim's Rapid^2 Therapy System

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

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Contact Person: Charles Hounsell

Date Prepared: December 11, 2014

Name of Device

Magstim Rapid^2 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

NeuroStar TMS Therapy System, Neuronetics, Inc. (K133408)

Device Description

The Rapid^2 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 Rapid^2 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 Rapid^2 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 Rapid^2 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 Rapid^2 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 Rapid^2 Therapy System is comprised of five principal components. These include:

1) User Interface;
2) Mainframe;
3) Power supply;
4) Air Film Coil;
5) Coil Stand
6) Accessory footswitch and
7) Accessory cables

The operator controls the Rapid^2 Therapy System via the User Interface, using a graphic LCD panel with touchscreen technology. The operator instructions, given through the User Interface, direct the Rapid^2 Stimulator mainframe in charging and discharging the device's high voltage discharge capacitor. The discharge is delivered to the treatment area via the Air Film Coil, which is positioned above the treatment area. Positioning, and fixation, of the coil over the treatment area is accomplished using the Coil Stand. The Rapid^2 power supply provides power to charge the high voltage capacitor in the Rapid2 Stimulator.

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

Non-Clinical Testing

Electrical safety and electromagnetic compatibility ("EMC") testing was conducted to demonstrate that the device is compliant with IEC 60601-1 (2nd & 3rd ed.) and IEC 60601-1-2 (2007). Environmental testing also demonstrated compliance with IEC 60601-1. The biocompatibility evaluation demonstrated that the coil meets ISO 10993-1 (2009) standards. In addition, magnetic field plots, and acoustic output measurements were also conducted to demonstrate safety and performance.

Software verification and validation testing further demonstrated that the software performs as intended and in accordance with specifications. The potential risks of Rapid^2 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.

The non-clinical testing with the Rapid^2 Therapy System included testing of the magnetic field characteristics of the system, as required by FDA's guidance document "Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems", as follows:

- **Output Waveform**

The output waveform produced by the biphasic figure 8 coil was measured using a calibrated search coil connected to an oscilloscope. This way the waveform could be quantified in three directions as well as in time.

- **Electric Field Spatial Distribution**

The electric field distribution was modeled using a finite element method on a homogeneous sphere with a radius of 8.5cm. This allows a quantification of the depth (d1/2) and spread (S1/2) of the field.

- **Magnetic Field Strength Gradient**

The magnetic field strength was measured in a relevant volume above the stimulating coils using a calibrated search coil connected to an oscilloscope. This way the magnetic field strength could be quantified in three directions as well as its magnitude.

- **Cooling System Test**

The temperature on the patient surface was measured over successive treatment sessions in order to evaluate the effectiveness of the cooling system at a higher than normal ambient temperature to ensure safe operation.

The performance tests demonstrate that the Rapid^2 Therapy System may be safely and effectively used for treatment of Major Depressive Disorder.

Substantial Equivalence

The Rapid^2 Therapy System has the same intended use and indications for use as the predicate device, as well as similar technological characteristics and principles of operation. The minor technological differences between the Rapid^2 Therapy System and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Rapid^2 Therapy System is as safe and effective as the predicate.

The design of the Rapid^2 Therapy System is similar to the design of the NeuroStar TMS Therapy System, 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.

Transcranial magnetic stimulation is enabled in the Rapid^2 Therapy System and in the NeuroStar TMS Therapy System, as both devices have the same system components, consisting of a mobile cart or console, an electromagnetic coil, a positioning arm, a TMS stimulator, and software. The basic operational procedure is the same in both the Rapid^2 Therapy System and in the NeuroStar TMS Therapy System consisting of system setup, patient preparation, determination of patient's motor threshold, coil position, and administration of treatment at predefined treatment stimulation parameters. The similarities and minor differences between the Rapid^2 Therapy System and the NeuroStar TMS Therapy System are described in the table below:

Table 1: Substantial Equivalence Summary

Criteria	Rapid^2 Therapy System	NeuroStar TMS Therapy System
Magnetic Field Intensity	120% of the MT	120% of the MT
Frequency	10 Hz	10 Hz
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/wk	5	5
Treatment Schedule	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks
Area of brain to be stimulated	Frontal Cortex	Frontal Cortex
Applicator Configuration **Core Material**	Biphasic Figure 8 Coil Air	Biphasic Figure 8 Coil Ferromagnetic
Coil Parameters	Area = 33000mm^2 Flat spiral winding WC = 1.75 mm × 6 mm N = 3x19 turns/wing × 2 wings	Area = 13000mm^2 Stranded rectangular windings Wire wrapped around cross-section of the core N = 5 turns/wing (stranded)
Machine Output Parameters: Amplitude in Standard Motor Threshold (SMT) units **Pulse width (usec)** **Frequency range (Hz)** **Pulse train duration range (sec)** **Inter-train interval range (sec)**	0.28 - 1.9 300 0.1 - 30 1 - 20 10 - 60	0.22 - 1.6 185 0.1 - 30 1 - 20 10 - 60

Criteria	Rapid^2 Therapy System	NeuroStar TMS Therapy System
Maximum trains per session	~ 140	~ 140
Maximum # of pulses per session (cumulative exposure)	5000	5000

The basic software capabilities related to treatment administration are the same in the Rapid^2 Therapy System and in the NeuroStar TMS Therapy System.

Both the Rapid^2 Therapy System and in the NeuroStar TMS Therapy System meet 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 Rapid^2 Therapy System and in the NeuroStar TMS Therapy System are identical. Furthermore, the key technological characteristics of the Rapid^2 Therapy System and in the NeuroStar TMS Therapy System, including basic design, mechanism of action, components, specifications, and treatment procedure, are similar. Performance testing demonstrates that the minor differences do not impact safety or effectiveness.

Thus, the Rapid^2 Therapy System is substantially equivalent to the NeuroStar TMS Therapy System predicate device.