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

March 10, 2017

Magstim Company Ltd.
Kevyn Beard, Regulatory Affairs Manager
Spring Gardens
Whitland, SA34 0HR
Carmarthenshire, GB

Re: K162935
Trade/Device Name: Rapid2 Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: February 2, 2017
Received: February 6, 2017

Dear Kevyn Beard:

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" (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 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

Digitally signed by William J. Heetderks -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -S
Date: 2017.03.10 08:59:02 -05'00'

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

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)*

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

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

Magstim Company Limited
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SA34 OHR, United Kingdom

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

Contact Person: Kevyn Beard

Date Prepared: February 2, 2017

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

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

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) Optional D70mm MT Remote Coil
6) Accessory coil stand
7) Accessory footswitch and
8) Accessory cables

The proposed change which is the subject of this 510(k), is to introduce a new optional hand held remote coil that is intended to be used for determining the motor threshold level.

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 patient via the stimulating coil. Motor threshold level can be determined using either the Air Film Coil or the optional D70mm MT Remote Coil. Treatment 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 an accessory 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 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, magnetic field measurements and acoustic output measurements have been 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", was demonstrated under K143531

The addition of the optional D70mm MT Remote Coil to the Rapid^2 Therapy System (predicate device) does not change the intended use and indications for use nor does it change the technological characteristics and principles of operation. The addition of the optional D70mm MT Remote Coil raises 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 similarities and minor differences between the Air Film Coil and optional D70mm MT Remote Coil are described in the table below:

Table 1: Substantial Equivalence Summary

Criteria	Rapid^2 System (Subject of this submission)		Rapid^2 Therapy System (Predicate System)
Manufacturer	Magstim Company Limited		Magstim Company Limited
Device Name	Rapid^2 System		Rapid^2 System
Clearance date			08/05/2015
510(k) number			K143531
Device code	OBP		OBP
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.		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.
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
Applicator (Coil) Parameters			
	D70 MT Remote Coil (Optional for MT Determination only)	Air Film Coil (Treatment Delivery and MT Determination)	Air Film Coil (Treatment Delivery and MT Determination)
Waveform	Biphasic	Biphasic	Biphasic
Configuration	Figure 8	Figure 8	Figure 8

Criteria	Rapid² System (Subject of this submission)		Rapid² Therapy System (Predicate System)
Core Material	Air	Air	Air
Coil Winding Parameters	Flat spiral winding 9 turns/wing 1.75 × 6mm wire	Flat spiral winding 19 turns/wing, 3 lyrs 1.0 × 3.5mm wire	Flat spiral winding 19 turns/wing, 3 layers 1.0 × 3.5mm wire
Inductance (nominal)	15µH	12µH	12µH
Pulse Width	330µs	300µs	300µs
Stimulator Output Parameters			
Amplitude in SMT units (Standard Motor Threshold)	0.28 - 1.9		0.28 - 1.9
Frequency range (Hz)	0.1 - 30		0.1 - 30
Pulse train duration range (sec)	1 - 20		1 - 20
Inter-train interval range (sec)	10 - 60		10 - 60
Maximum trains per session	~ 140		~ 140
Maximum # of pulses per session (cumulative exposure)	5000		5000
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
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 unchanged from the predicate device.

[redacted]

The Rapid^2 Therapy System meets the same electrical and mechanical safety standards (IEC 60601-1) and the same EMC standards (IEC 60601-1-2), with or without the optional D70mm MT Remote Coil.

Conclusions

In summary, the addition of the D70mm MT Remote Coil does not change the intended use and indications for use for the Rapid^2 Therapy System, nor does it change the technological characteristics and principles of operation, including basic design, mechanism of action, specifications and treatment procedure. The addition of the optional D70mm MT Remote Coil raises no new issues of safety and effectiveness. Performance data demonstrate that the Rapid^2 Therapy System is as safe and effective as the predicate.

Thus, the Rapid^2 Therapy System, with the addition of the D70mm MT Remote Coil, is substantially equivalent to the predicate device.