May 4, 2018

Mag & More GmbH
Kerstin Haringer
Regulatory Affairs and Quality Assurance
Machtlfinger Strasse l3
Munich, 81379 De

Re: K180313
Trade/Device Name: Apollo TMS Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: January 26, 2018
Received: February 5, 2018

Dear Kerstin Haringer:

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.

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.

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,

William J. Heetderks -S
2018.05.04 17:04:25 -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)*

Device Name
Apollo TMS Therapy System

Indications for Use *(Describe)*
The Apollo 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.

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

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510(k) SUMMARY

I. SUBMITTER

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Contact Person: Dr. Kerstin Häringer
Date prepared: January 26, 2018

II. DEVICE

Name of Device	**Apollo TMS Therapy System**
Common or Usual Name	Repetitive Transcranial Magnetic Stimulation (rTMS) System
Classification Name	Repetitive transcranial magnetic stimulation (rTMS) system (21 CFR 882.5805)
Regulatory Class	II
Product Code	OBP

III. PREDICATE DEVICES

NeuroStar TMS Therapy System, Neuronetics, Inc. (**K161519**), decision date September 11, 2016
Rapid² Therapy System, Magstim Ltd., (**K162935**), decision date March 10, 2017
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Apollo TMS Therapy System is an electromagnetic device that non-invasively delivers a rapidly pulsed magnetic field to the cerebral cortex in order to activate neurons within a limited volume without inducing a seizure. This method of cortical stimulation by application of brief magnetic pulses to the head is known as Transcranial Magnetic Stimulation.

The Apollo TMS Therapy System is comprised of four principal components. These include:

- User Interface
- Main Unit
- Stimulation Coil
- Coil Positioning System

The operator controls the Apollo TMS Therapy System via the User Interface. The Treatment and Data Management Software administrates the treatment protocols and the patient´s individual stimulation dose determined by the patient´s individual motor threshold. The stimulation is applied via the Stimulation Coil which is positioned to the left dorsolateral prefrontal cortex (DLPFC) by means of the coil positioning system. The observed and documented increase in cortical excitability after high frequency (10Hz) rTMS has been shown to persist beyond the duration of the train of stimulation.

Both devices, the Apollo TMS Therapy System and the predicate device have equivalent system components, consisting of a main unit containing the stimulator, a stimulation coil, a coil positioning system, and software. The basic operational procedure is identical consisting of system setup, patient preparation, coil positioning, determination of patient's motor threshold, and administration of treatment at predefined treatment stimulation parameters.

V. INDICATIONS FOR USE

The Apollo 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both systems, the Apollo TMS Therapy System and the predicate device use the technology named Transcranial Magnetic Stimulation (TMS). TMS makes use of electromagnetic induction to activate and modulate cortical neurons.
The similarities and minor differences between the Apollo TMS Therapy System and the Predicates are listed in the table below.

Characteristics of the device as compared to the predicate devices

DESCRIPTIVE INFORMATION	Apollo TMS Therapy System	NeuroStar TMS Therapy System	Rapid² Therapy System
Indications for Use	The Apollo 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 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 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 Stimulation Parameters			
1. Area of brain to be stimulated	1. Left DLPFC	1. Left DLPFC	1. Left DLPFC
2. Stimulation intensity	2. 120% of MT	2. 120% of MT	2. 120% of MT
3. %MT range	3. 50% to 150% MT	3. 25% to 140% MT	3. 0% to 200% MT
4. Stimulation frequency	4. 10 Hz	4. 10 Hz	4. 10 Hz
5. Pulse train duration	5. 4 sec	5. 4 sec	5. 4 sec
6. Inter-train interval	6. 11 – 26 sec	6. 11 – 26 sec	6. 26 sec
7. Trains per session	7. 75	7. 75	7. 75
8. Max No. of Pulses	8. 3,000	8. 3,000	8. 3,000
Output Stimulation Parameters			
1. Amplitude in SMT units	1. 0 – 2.0 SMT	1. 0.22 – 2.08 SMT	1. 0.28 – 1.9 SMT
2. Pulse width (± accuracy)	2. 167 µs (± 10%)	2. 185 µs (± 10%)	2. 300 µs (± 10%)
3. Frequency (± accuracy)	3. 0-100 Hz (± 2%)	3. 0.1-30 Hz (± 2%)	3. 0.1-30 Hz (± 2%)
Stimulation Coil Parameters			
1. Configuration	1. Figure 8 Coil	1. Figure 8 Coil	1. Figure 8 Coil
2. Core material	2. Air	2. Iron Core	2. Air

Coil Positioning System	Integrated into Head-and-Neck-Support System, Landmark-Aided Coil Placement	Integrated into Head Support System, Laser-Aided Coil Placement	Cap positioned in relation to nasion

PERFORMANCE DATA

Non-Clinical Testing

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

The data presented demonstrates that the Apollo TMS Therapy system is in summary adequate to the Predicate Devices. Furthermore tests show that the major characteristics of the Apollo TMS Therapy system and the Predicate Devices are similar and that the minor differences do not impact safety or effectiveness. Both systems are very similar in function, safety and therapeutic benefit. In conclusion, the Apollo TMS Therapy system is as safe, as effective, and performs as well as the predicate device.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and electromagnetic compatibility (EMC) testing were conducted on the Apollo TMS Therapy System. The system complies with the IEC 60601-1:2005 MOD (IEC 60601-1:2005 +AMD1:2012) standard for basic safety and essential performance and the IEC 60601-1-2:2007 standard for electromagnetic compatibility.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device is considered as a "moderate level of concern" (supported by Special Controls Guidance "rTMS Class II"), since a failure or latent design flaw could either directly result in minor injury to the patient or operator or could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Risk management

The potential risks of the Apollo TMS Therapy System have been identified and evaluated in compliance with ISO 14971:2007 and were determined to be acceptable, or have been addressed with risk control measures.

VII. CONCLUSION

Substantial Equivalence

The indication for use, the patient population, the treatment procedure, and all relevant protocol parameters (stimulation intensity, stimulation frequency, number of pulses in a train, numbers of trains, number of treatment sessions) are identical for the Apollo TMS Therapy System and the Predicate Devices. The identified minor differences between the systems are without any known impact on safety or efficacy.

The figure-of-eight coil design, the coil positioning method and the electromagnetic characteristics of the Apollo TMS Therapy System and the Predicate Devices are equivalent.

The Apollo TMS Therapy System does not introduce any new safety considerations in comparison to the Predicate Devices.

The above comparison, demonstrates and supports the substantial equivalency of the Apollo TMS Therapy System to the Predicate Devices.