May 24, 2024

MAG & More GmbH
Juliane Rieß
Regulatory Affairs Manager
Machtlfinger Straße 13
Munich, 81379
Germany

Re: K232639
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: April 30, 2024
Received: April 30, 2024

Dear Juliane Rieß:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Pamela Scott, MS
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232639

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.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

510(k) Owner:	MAG & More GmbH Machtlfinger Straße 13 81379 Munich, Germany Phone: +49 (0)89 998 292 300 Fax: +49 (0)89 998 292 301
Primary Contact:	Juliane Rieß
Date Prepared:	30-Apr-2024
Proprietary Name:	Apollo TMS Therapy System
Common/Usual Name:	Repetitive Transcranial Magnetic Stimulation (rTMS) System
Classification Name:	Repetitive Transcranial Magnetic Stimulation Device 21 CFR 882.5805, Product Code OBP
Predicate Device:	HORIZON ® TMS Therapy System (K182853) Apollo TMS Therapy System (K180313)

Intended 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.

Device Description and Function

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 (TMS).

The Apollo TMS Therapy System is comprised of the following principal components:

- User Interface
- Main Unit (with or without housing)
- Stimulation Coil
- Coil Positioning System

The operator controls the Apollo TMS Therapy System via the user interface (application software “Stimware”). “Stimware” is a treatment and data management software that administrates treatment protocols and the patient´s individual stimulation dose determined by the patient´s individual motor threshold. Stimulation is applied via the stimulation coil which is positioned to the left dorsolateral

prefrontal cortex (DLPFC) by means of a 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.

Performance Standards

The Apollo TMS Therapy System conforms to the following recognized consensus standards:

- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62304 Medical device software - Software life cycle processes

Further Applicable Standards

The Apollo TMS Therapy System complies with applicable requirements of the following additional standards:

- ISO 14971 Medical devices - Application of risk management to medical devices
- ISO 15223 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
- IEC 81001-5-1 Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle

Non-Clinical and Clinical Performance Data

The contents of this 510(k) complies with the FDA Guidance Document: “Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems - Guidance for Industry and Food and Drug Administration Staff.” Non-clinical performance testing was performed according to the standards listed above, including electrical safety, electromagnetic compatibility and biocompatibility as required and already cleared by the FDA earlier in K180313. To establish substantial equivalence for the additional coils PMD70-pCool, HANS-aCool, PMD70-aCool and the HANS-Coil cleared by the FDA earlier in K180313, a comparative testing of the technological characteristics has been performed. Configuration, technological characteristics, and magnetic field characteristics are substantially equivalent to the predicate devices.

The clinical performance of iTBS depends on the stimuli being delivered at equal intensity, to ensure that a constant dose of stimuli is maintained during treatment. Clinical data on treatment efficacy of the iTBS protocol has already been demonstrated in Summary K173620. Additional verification testing has demonstrated that the intensity of the individual stimuli in iTBS is equal and kept constant throughout the delivery of the full treatment. This was successfully demonstrated for the pCool coils and aCool coils of the subject device and therefore, is substantially equivalent to the primary predicate

HORIZON ® TMS Therapy System (cleared in K182853). Additional clinical performance data is not required to demonstrate safety and effectiveness of the iTBS treatment.

Software Verification and Validation Testing

Software verification and validation testing was conducted and documented in accordance with IEC 62304 and the 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 documentation for this device is considered as "basic documentation" (supported by Special Controls Guidance "rTMS Class II"), since a failure or flaw of any device software function(s) could not present a hazardous situation with a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use.

Risk Management

Risk assessment is applied throughout the product development lifecycle process in accordance with the requirements set forth under the Agency recognized consensus standards ISO 14971 and IEC 62304. The results of the comprehensive risk analysis for the device indicate that there are no new hazards, harms, or safety risks introduced when compared to the predicate devices. Furthermore, the iTBS protocol is a well-established stimulation protocol, that has shown similar side-effects and safety compared to the standard stimulation protocol (Blumberger et al. 2018[1]).

Substantial Equivalence

The Apollo TMS Therapy System is substantially equivalent to its predicate devices, the HORIZON® TMS Therapy System (K182853) and Apollo TMS Therapy System (K180313). The intended use and indications for use for the Apollo TMS Therapy System and predicate devices are identical.

The Apollo TMS Therapy System and the secondary predicate device have equivalent system components, consisting of a main unit (available in two variants 918001 Apollo and 918010 Apollo Light) including the stimulator, a stimulation coil, a coil positioning system, and the application 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.

Treatment efficacy depends on the applied treatment protocol. The iTBS protocol of the subject device Apollo TMS Therapy System is identical to that of the primary predicate device HORIZON ® TMS Therapy System cleared in K182853. The clinical performance of iTBS depends on the stimuli being delivered at equal intensity, to ensure that a constant dose of stimuli is maintained during treatment. The equal and constant intensity of individual stimuli being delivered was successfully demonstrated for the pCool coils (510570 HANS-pCool, 510565 PMD70-pCool) and aCool coils (510580 HANS-aCool, 510575 PMD70-aCool) of the subject device throughout the full iTBS treatment. Therefore, the subject device is substantially equivalent to the primary predicate HORIZON ® TMS Therapy System (K182853) in terms of iTBS treatment.

The HANS-coil already cleared in K180313 is identical to the HANS-pCool and to the PMD70-pCool (PMD70-pCool without the exterior plastic adapter). Both, the pCool and aCool coils of the subject device Apollo TMS Therapy System have the identical coil winding configuration compared to the HANS-Coil cleared in K180313 and thus can be considered as substantially equivalent. The minor difference in the cooling technology between the aCool coils of the subject device, and the HANS-Coil of the Apollo TMS Therapy System cleared in K180313 does not alter the electromagnetic field profile or the stimulation efficacy.

Conclusions

The indication for use, the target population, the treatment procedure, and the treatment spot are all 100 % identical for the Apollo TMS Therapy System and the predicate devices HORIZON ® TMS Therapy System (K182853) and Apollo TMS Therapy System (K180313).

The performance and the clinical effectiveness are substantially equivalent and the iTBS treatment parameters are identical to those of the primary predicate device HORIZON ® TMS Therapy System (K182853). Non-clinical performance testing has demonstrated that the technological characteristics of the aCool-coils (HANS-aCool and PMD70-aCool) and the PMD70-pCool of the subject device are substantially equivalent to the HANS-coil of the secondary predicate Apollo TMS Therapy System (K180313). Additional verification testing has demonstrated that the intensity of the individual stimuli in iTBS is equal and kept constant throughout the delivery of the full treatment with the Apollo TMS Therapy System. This provides a consistent treatment dose that is clinically effective when treating patients with the Apollo TMS Therapy System. This demonstrates that the Apollo TMS Therapy System is as safe and effective for use in treatment of Major Depressive Disorder as the primary predicate device.

All identified differences between the subject device Apollo TMS Therapy System and its predicate devices are minor and without any impact on safety or effectiveness. The subject device Apollo TMS Therapy System does not introduce any new safety considerations.

Therefore, the Apollo TMS Therapy System can be considered to be substantially equivalent to its predicate devices HORIZON ® TMS Therapy System (K182853) and Apollo TMS Therapy System (K180313).

[1] Daniel M Blumberger, Fidel Vila-Rodriguez, Kevin E Thorpe, Kfir Feffer, Yoshihiro Noda, Peter Giacobbe, Yuliya Knyahnytska, Sidney H Kennedy, Raymond W Lam, Zafiris J Daskalakis, Jonathan Downar: Effectiveness of theta burst versus high-frequency repetitive transcranial magnetic stimulation in patients with depression (THREE-D): a randomised non-inferiority trial; The Lancet 391:10131, 1637-1748

Substantial Equivalence Comparison

Characteristic	Subject Device	Predicate Device	Secondary Predicate
510(k) Number	K232639	K182853	K180313
Device Trade Name	Apollo TMS Therapy System	HORIZON ® TMS Therapy System	Apollo TMS Therapy System
510(k) submitter	MAG & More GmbH Machtlfinger Straße 13 81379 Munich, Germany	Magstim Company Limited Spring Gardens, Whitland, Carmarthenshire SA34 OHR, United Kingdom	MAG & More GmbH Machtlfinger Straße 13 81379 Munich, Germany
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 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 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.
Product Code	OBP	OBP	OBP
Classification	21 CFR 882.5805	21 CFR 882.5805	21 CFR 882.5805
Standard Treatment Stimulation Parameters			
Area of brain to be stimulated	Left DLPFC	Left DLPFC	Left DLPFC
Stimulation intensity	120% of MT	120% of MT	120% of MT
%MT range	50% to 150% MT	0% to 200% MT	50% to 150% MT

Characteristic	Subject Device		Predicate Device			Secondary Predicate
Stimulation frequency	10 Hz		10 Hz			10 Hz
Pulse train duration	4 sec		4 sec			4 sec
Inter-train interval	11 – 26 sec		11 – 26 sec			11 – 26 sec
Trains per session	75		75			75
Max No. of Pulses	3,000		3,000			3,000
Output Stimulation Parameters						
Amplitude in SMT units	0 – 2.0 SMT		0.28 - 1.9 SMT			0 – 2.0 SMT
Pulse width (± accuracy)	pCool coils: HANS-pCool PMD70-pCool 162 µs ± 1.9 µs	aCool coils: HANS-aCool PMD70-aCool 163 µs ± 2.5 µs	HORIZON® MT Remote Coil 330 µs	HORIZON® E-z Cool Coil 340 µs	HORIZON® AFC 300 µs	HANS-Coil 167 µs (± 10%)
Frequency (± accuracy)	30-100 Hz (± 2%)		1 – 20 Hz			30-100 Hz (± 2%)

Characteristic	Subject Device		Predicate Device			Secondary Predicate
Stimulation Coil Parameters						
Coil	pCool coils: HANS-pCool PMD70-pCool	aCool coils: HANS-aCool PMD70-aCool	HORIZON® MT Remote Coil	HORIZON® E-z Cool Coil	HORIZON® AFC	HANS-Coil
Configuration	figure-of-eight coil		figure-of-eight coil			figure-of-eight coil
Output waveform	biphasic		biphasic			biphasic
Cooling	passive cooling	active air-cooling	air			passive cooling
Coil winding: N	10 on each side		9 on each side	3x23 on each side	3x19 on each side	10 on each side
Coil winding: inner diameter	20 mm		55 mm	37.5 mm	43 mm	20 mm
Coil winding: outer diameter	80 mm		92 mm	97 mm	92 mm	80 mm
Coil winding: wire diameter	6.4 mm * 2.9 mm		-	-	-	6.4 mm * 2.9 mm
Surface tempera-ture at max output	< 48 °C for less than 10 minutes using iTBS protocol		-			< 48 °C for less than 10 minutes using iTBS protocol

Characteristic	Subject Device	Predicate Device	Secondary Predicate
Coil Positioning System	Integrated into Head-and-Neck-Support System (HANS), Landmark-Aided Coil Placement TMS Cap for standardized 10-20-EEG Positioning with Coil Positioning Arm	TMS Patient Caps	Integrated into Head-and-Neck-Support System (HANS), Landmark-Aided Coil Placement
iTBS Treatment Protocol			
Area of brain to be stimulated	Left DLPFC	Left DLPFC	-
Stimulation Intensity	120% of the MT	120% of the MT	-
Repetition Rate	50 Hz (5 pulses per sec)	50 Hz (5 pulses per sec)	-
Train Duration	2 sec	2 sec	-
Inter-train Interval	8 sec	8 sec	-
Burst Pulses	3	3	-
Bursts	200	200	-
Inter Pulse interval	20 ms	20 ms	-
Number of trains	20	20	-
Number of Pulses per Session	600	600	-

Characteristic	Subject Device	Predicate Device	Secondary Predicate
Treatment Session Duration	3.09 min	3.09 min	-
Sessions/week	5	5	-
Treatment Schedule	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks	-