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U.S. FOOD & DRUG ADMINISTRATION

September 4, 2025

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

Re: K243700
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: November 29, 2024
Received: November 29, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

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Pamela D. Scott
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
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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)*

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 and as an adjunct for the treatment of MDD in adolescent patients (age 15-21).

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

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)89 998 292 330
Primary Contact:	Juliane Rieß
Date Prepared:	03-Jul-2025
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:	NeuroStar Advanced Therapy System (K231926) Apollo TMS Therapy System (K180313, K232639)

Intended Use

The Apollo TMS Therapy System is indicated for the treatment of major depressive disorder (MDD) in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode and as an adjunct for the treatment of MDD in adolescent patients (age 15-21).

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. For the treatment of major depressive disorder, the stimulation coil is positioned to the left dorsolateral prefrontal cortex (DLPFC) by means of the coil positioning system.

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

Apollo TMS Therapy System and its technological characteristics remain identical to that cleared within K180313 and K232639. No hardware changes have been made to the subject device, and no change to the treatment protocols was made.

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 and already cleared by the FDA earlier in K180313 and K232639. To establish substantial equivalence between the predicate device and the subject device comparative performance testing was carried out. The data provided in this submission, such as the comparison of the electric and magnetic field output of the device, demonstrate that expanding the indications to include the adjunct treatment of major depressive disorder (MDD) in adolescent patients (aged 15–

21) does not raise any different questions regarding safety and effectiveness. The effectiveness and safety of the adjunctive treatment of adolescent patients (15-21) suffering from MDD has been demonstrated for the primary predicate device (K231926) by a large-scale retrospective analysis of real-world data and a systematic literature review. The data demonstrated a substantially equivalent treatment effect of TMS therapy as an adjunct to antidepressant therapy over antidepressant therapy alone in reducing depression in adolescents. Furthermore, The authors of the studies included in the literature review concluded that TMS is well tolerated and safe for adolescents. No additional clinical data is necessary to demonstrate safety and effectiveness.

Software Verification and Validation Testing

Software verification and validation testing was conducted and documented in accordance with IEC 62304 and internal quality procedures considered a well-established method as already used in K180313 and K232639. 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." No software changes have been made to the subject device.

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.

The proposed changes for the subject device for the adjunctive treatment of adolescent patients (15-21) suffering from major depressive disorder (MDD) are limited to updates to the IFU. These changes have been made to enable the safe and effective treatment of adolescent patients (15-21) suffering from MDD and do not introduce any new safety or effectiveness considerations.

Substantial Equivalence

The Apollo TMS Therapy System described here is identical to the one already cleared in K180313 and K232639 for the treatment of major depressive disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

The Apollo TMS Therapy System is substantially equivalent to its predicate devices, the NeuroStar Advanced Therapy System (K231926) and Apollo TMS Therapy System (K180313, K232639). The intended use and indications for use for the Apollo TMS Therapy System and predicate devices are equivalent. The Apollo TMS Therapy System and the secondary predicate device have identical 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, and consists of system setup, patient preparation, coil positioning, determination of patient's motor threshold, and administration of treatment at predefined treatment stimulation parameters. Technological characteristics of the subject device are substantially equivalent to the primary predicate device NeuroStar Advanced Therapy System (K231926).

Conclusions

The indication for use, the target population, the treatment procedure, and the treatment spot are identical for the Apollo TMS Therapy System and the predicate devices NeuroStar Advanced Therapy System (K231926) and Apollo TMS Therapy System (K180313, K232639).

The comparative non-clinical performance testing, such as the comparison of the electric and magnetic field output of the device, demonstrate that the Apollo TMS Therapy System is substantially equivalent to the predicate devices. All identified differences between the subject device, the Apollo TMS Therapy System, and its primary predicate device are minor and do not raise different questions of safety or effectiveness. This demonstrates that the Apollo TMS Therapy System is as safe and effective for use as an adjunct for treatment of adolescent patients (15-21) suffering from major depressive disorder as the primary predicate device.

Therefore, the Apollo TMS Therapy System is substantially equivalent to its predicate devices NeuroStar Advanced Therapy System (K231926) and Apollo TMS Therapy System (K180313, K232639).

Substantial Equivalence Comparison

Characteristic	Subject Device	Predicate Device	Secondary Predicate
510(k) Number	N/A	K231926	K180313, K232639
Device Trade Name	Apollo TMS Therapy System	NeuroStar Advanced Therapy System	Apollo TMS Therapy System
510(k) submitter	MAG & More GmbH Machtlfinger Straße 13 81379 Munich, Germany	Neuronetics, Inc. 3222 Phoenixville Pike Malvern, PA 19355	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 and as an adjunct for the treatment of MDD in adolescent patients (age 15-21).	NeuroStar Advanced Therapy is indicated as an adjunct for the treatment of Major Depressive Disorder (MDD) in adolescent patients (15-21).	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.
Target population	Adult and Adolescent patients age 15-21	Adolescent patients age 15-21	Adult patients
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

Characteristic	Subject Device	Predicate Device	Secondary Predicate
Stimulation intensity	120% MT with allowable adjustments	120% MT with allowable adjustments	120% of MT
%MT range	50% to 150% MT	25% to 140% MT	50% to 150% MT
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
Stimulation parameter ranges			
Amplitude in SMT units	0 – 2.0 SMT	0.22 – 2.08 SMT	0 – 2.0 SMT
Pulse width (± accuracy)	pCool coils: 162 µs ± 1.9 µs aCool coils: 163 µs ± 2.5 µs	185 µs	pCool coils: 162 µs ± 1.9 µs aCool coils: 163 µs ± 2.5 µs
Pulse train duration (sec)	0.04 - 2000	1 - 600	0.04 - 2000
ITI range (sec)	1 - 65	0 - 600	1 - 65
Max # of pulses per session	75,000	5,000	75,000

Characteristic	Subject Device		Predicate Device	Secondary Predicate	
Stimulation Coil Parameters					
Coil	pCool coils: HANS-pCool PMD70-pCool	aCool coils: HANS-aCool PMD70-aCool	Ferromagnetic Coil	pCool coils: HANS-pCool PMD70-pCool	aCool coils: HANS-aCool PMD70-aCool
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	active air-cooling
E-Field at 1.0 SMT	130 V/m		135 V/m	130 V/m	
Coil Positioning System	Integrated into Head-and-Neck support system, landmark-aided coil placement or TMS cap for standardized 10-20-EEG positioning with coil positioning arm		Integrated into Head Support System Laser-aided coil placement	Integrated into Head-and-Neck support system, landmark-aided coil placement or TMS cap for standardized 10-20-EEG positioning with coil positioning arm	
iTBS Treatment Protocol					
Area of brain to be stimulated	Left DLPFC		Left DLPFC	Left DLPFC	
Stimulation Intensity	80 - 120% MT with allowable adjustments		80 - 120% MT with allowable adjustments	120% of the MT	
Repetition Rate	50 Hz (5 pulses per sec)		50 Hz (5 pulses per sec)	50 Hz (5 pulses per sec)	
Train Duration	2 sec		2 sec	2 sec	
Inter-train Interval	8 sec		8 sec	8 sec	

Characteristic	Subject Device	Predicate Device	Secondary Predicate
Burst Pulses	3	3	3
Bursts	200	200	200
Inter Pulse interval	20 ms	20 ms	20 ms
Number of trains	20	20	20
Number of Pulses per Session	600	600	600

NOTE: Only the standard and iTBS treatment protocol parameters have been cleared. Other stimulation parameters have not been cleared or evaluated for safety and effectiveness.