



August 18, 2025

Juliane Rieß
Regulatory Affairs Manager
Machtlfinger Straße 13
Munich, 81379
Germany

Re: K243539

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, QCI
Dated: July 4, 2025
Received: July 16, 2025

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,

JAY R. GUPTA -S

For Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K243539

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, as well as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

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)89 998 292 330
Primary Contact:	Juliane Rieß
Date Prepared:	04-Jul-2025
Proprietary Name:	Apollo TMS Therapy System
Common/Usual Name:	Repetitive Transcranial Magnetic Stimulation (rTMS) System
Classification :	21 CFR 882.5805, class II, product code OBP and QCI
Predicate Device:	HORIZON [®] 3.0 TMS Therapy System (K222171) Apollo TMS Therapy System (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, as well as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

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. The observed and documented increase in cortical excitability after high frequency rTMS has been shown to persist beyond the duration of the train of stimulation. For treatment of OCD, the stimulation coil is positioned to the dorsomedial prefrontal cortex (DMPFC).

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 the prior Apollo TMS Therapy System clearance (K232639).

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 or leveraged from prior clearances of the device (K180313 and K232639) if unchanged, including electrical safety, electromagnetic compatibility and biocompatibility testing.

The proposed changes for the subject device for the adjunctive treatment of OCD are limited to updates to the Indications for Use (IFU) and the Stimware application software, in addition to necessary labeling changes. These changes have been made to enable the safe and effective treatment of patients with OCD and do not introduce any new safety or effectiveness considerations.

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 obsessive-compulsive disorder (OCD) in adult patients does not raise any different questions regarding safety and effectiveness. Further performance testing was carried out to demonstrate that the Apollo TMS Therapy System can reliably and safely deliver the OCD protocol while remaining within recognized safety temperature limits. This verification is based on well-established methods using the recognized international standard IEC 60601-1 and the test protocol and data already used in K180313 and K232639.

Additional verification testing has demonstrated that the intensity of each stimulus during the OCD protocol is equal and kept constant throughout the delivery of the full treatment. This was successfully demonstrated for the subject device and therefore, is substantially equivalent to the primary predicate HORIZON[®] 3.0 TMS Therapy System (cleared in K222171). Clinical performance data was not required to demonstrate safety and effectiveness of the OCD treatment.

Software Verification and Validation Testing

Software verification and validation testing was conducted and documented in accordance with IEC 62304 and internal quality procedures 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."

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 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.

Substantial Equivalence

The Apollo TMS Therapy System is substantially equivalent to its predicate devices, the HORIZON[®] 3.0 TMS Therapy System (K222171) and Apollo TMS Therapy System (K232639). 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 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 consisting of system setup, patient preparation, coil positioning, determination of patient's motor threshold, and administration of treatment at predefined treatment stimulation parameters.

Treatment effectiveness depends on the applied treatment protocol. The OCD protocol of the subject device Apollo TMS Therapy System is identical to that of the primary predicate device HORIZON[®] 3.0 TMS Therapy System cleared in K222171. The equal and constant intensity of individual stimuli being delivered was successfully demonstrated for the subject device throughout the full OCD treatment. Additionally, although the waveform characteristics (e.g., pulse width) differ, the output stimulation of the system are adequately similar to determine the subject device is substantially equivalent to the primary predicate HORIZON[®] 3.0 TMS Therapy System (K222171) in terms of OCD treatment.

Conclusions

The indication for use, the target population, the treatment procedure, and the treatment spot for OCD are all identical for the Apollo TMS Therapy System and the predicate device HORIZON[®] 3.0 TMS Therapy System (K222171). The MDD treatment of the subject device was already cleared in K232639 and remains unaltered.

The OCD treatment parameters are identical to those of the primary predicate device HORIZON[®] 3.0 TMS Therapy System (K222171). Non-clinical performance testing has demonstrated that the technological characteristics of the subject device are substantially equivalent to the predicate devices. Additional verification testing has demonstrated that the intensity of individual stimuli during the OCD protocol is equal and kept constant throughout the delivery of the full treatment with the Apollo TMS Therapy System. This provides a consistent treatment dose 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 adjunctive treatment of obsessive-compulsive 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 is substantially equivalent to its predicate devices HORIZON[®] TMS Therapy System (K222171) and Apollo TMS Therapy System (K232639).

Substantial Equivalence Comparison

Characteristic	Subject Device	Predicate Device	Secondary Predicate
510(k) number	N/A	K222171	K232639
Device trade name	Apollo TMS Therapy System	HORIZON [®] 3.0 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, as well as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).	Horizon 3.0 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, as well as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).	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, QCI	OBP, QCI	OBP
Classification	21 CFR 882.5805	21 CFR 882.5805	21 CFR 882.5805

Characteristic	Subject Device	Predicate Device	Secondary Predicate
<i>OCD Treatment Stimulation Parameters</i>			
Area of brain to be stimulated	DMPFC	DMPFC	-
Stimulation intensity	100 % of leg MT	100 % of leg MT	-
Stimulation frequency	20 Hz	20 Hz	-
Pulse train duration	2 sec	2 sec	-
Inter-train interval	20 sec	20 sec	-
Trains per session	50	50	-
Max no. of pulses	2000	2000	-
Treatment schedule	5 daily sessions for 5 weeks, 4 daily sessions for 1 week	5 daily sessions for 5 weeks, 4 daily sessions for 1 week	-
<i>Standard MDD Treatment Stimulation Parameters</i>			
Area of brain to be stimulated	Left DLPFC	Left DLPFC	Left DLPFC
Stimulation intensity	120% of MT	120% of MT	120% of MT
Stimulation frequency	10 Hz	10 Hz	10 Hz

Characteristic	Subject Device	Predicate Device	Secondary Predicate
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
Treatment schedule	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks
<i>iTBS Treatment Stimulation Parameters</i>			
Area of brain to be stimulated	Left DLPFC	Left DLPFC	Left DLPFC
Stimulation intensity	120% of the MT	120% of the MT	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
Burst pulses	3	3	3
Bursts	200	200	200
Inter pulse interval	20 ms	20 ms	20 ms
Number of trains	20	20	20

Characteristic	Subject Device	Predicate Device	Secondary Predicate
Number of pulses per session	600	600	600
Treatment session duration	3.09 min	3.09 min	3.09 min
Sessions/week	5	5	5
Treatment schedule	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks
Output Stimulation Parameters			
Amplitude in SMT units /SMT: standard motor-threshold)	0 – 2.0 SMT	0.28 - 1.9 SMT	0 – 2.0 SMT
Pulse width (\pm accuracy)	pCool coils: 162 μ s aCool coils: 163 μ s	HORIZON [®] MT Remote Coil: 330 μ s HORIZON [®] 3.0 E-z Cool Coil: 340 μ s	pCool coils: 162 μ s aCool coils: 163 μ s
Frequency (\pm accuracy)	1-100 Hz (\pm 2%)	1 – 20 Hz	30-100 Hz (\pm 2%) (iTBS)
Pulse train duration (sec)	0.04 - 2000	0.1 - 600	0.04 - 2000
ITI range (sec)	1 - 65	1 - 540	1 - 65
Max # of pulses per session	75,000	60,000	75,000

Characteristic	Subject Device	Predicate Device	Secondary Predicate
Stimulation Coil Parameters			
Configuration	figure-of-eight coil	figure-of-eight coil	figure-of-eight coil
Output waveform	biphasic	biphasic	biphasic
E-Field at 1.0 SMT	130 V/m	130 V/m	130 V/m
Surface temperature at max output	Remaining within recognized safety temperature limits	Remaining within recognized safety temperature limits	Remaining within recognized safety temperature limits
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 TMS Cap for standardized 10-20-EEG Positioning with Coil Positioning Arm