May 22, 2026

Tonica Elektronik A/S
% Kirstine Klitgaard Schou
Senior Medical Affairs Specialist
MagVenture A/S
Lucernemarken 15
Farum, DK-3520
Denmark

Re: K260189
Trade/Device Name: MagVenture Accelerated TMS (aTMS) Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: April 13, 2026
Received: April 13, 2026

Dear Kirstine Klitgaard Schou:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

ROBERT KANG -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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260189

Please provide the device trade name(s).

MagVenture Accelerated TMS (aTMS) Therapy System

Please provide your Indications for Use below.

The MagVenture Accelerated TMS Therapy System is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

Date Prepared: May 20, 2026

I. SUBMITTER

Tonica Elektronik A/S
Lucernemarken 15
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Primary Contact: Kirstine Klitgaard Schou, Ph.D
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II. DEVICE

Device Trade Name: MagVenture Accelerated TMS (aTMS) Therapy System

Classification Names: Repetitive transcranial magnetic stimulation system

Regulation: 21 CFR 882.5805

Regulatory Class: Class II

Device Panel: Neurology

Product Classification Code: OBP

III. PREDICATE DEVICES

Primary Predicate:

Device Name: Magnus Neuromodulation System
510(k) Number: K220177
Manufacturer: Magnus Medical, Inc.

Secondary Predicate:

Device Name: MagVenture TMS Therapy System
510(k) Number: K251119
Manufacturer: Tonica Elektronik A/S

IV. DEVICE DESCRIPTION

The MagVenture aTMS Therapy System is a transcranial magnetic stimulation device. Specifically, it is a computerized, electromechanical medical device that produces and delivers non-invasive magnetic fields to induce electrical currents targeting specific regions of the cerebral cortex. Transcranial magnetic stimulation (TMS) is a non-invasive technique used to apply brief magnetic pulses to the brain. The pulses are administered by passing high currents through an electromagnetic coil placed adjacent to a patient's scalp. They generate an electric field in the underlying brain tissue. When this field surpasses a specific threshold and aligns appropriately with the brain's neuronal pathways, it induces localized axonal depolarization, leading to neuron activation in the targeted brain region.

The MagVenture aTMS Therapy System represents an integrated system comprised of the following components:

- Magnetic Stimulator (MagPro Family)
- Coil for motor threshold determination: C-B60, C-B70
- Treatment Coils: Cool-B65, Cool-B70, T65, Cool D-B80
- Accessories:
    - Trolley with mounting for super flexible arm and coil holder arrangement
    - Super flexible arm or Flow Arm for coil fixation
    - Isolation transformer
    - Cooler Unit
    - Caps and Marking accessory (marking plate, pen, ruler) – Beam F3 or 5.5 cm Coil Placement
    - Vacuum pump and Vacuum pillow with Pillowcase for patient head fixation (Optional)
    - Treatment Chair (Optional)
    - Coil Hub (Optional)
    - MagVenture TMS Atlas Neuro Navigation System (Optional)

All components have previously received FDA clearance. The MagVenture aTMS Therapy System and its technological characteristics remain essentially the same as those cleared under K251119 and K220177.

This submission is a labeling expansion to include accelerated TMS protocols (multiple daily sessions) for both repetitive TMS (rTMS) and intermittent theta burst stimulation (iTBS), in addition to the standard once-daily regimens. No changes are made to hardware, software, stimulation output, waveform, or safety systems.

V. INDICATIONS FOR USE STATEMENT

The MagVenture TMS Therapy System is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode.

VI. SUBSTANTIAL EQUIVALENCE DISCUSSION

Table 1 provides a side-by-side comparison of the subject device and the primary predicate (K220177) and secondary predicate (K251119), including intended use, indications for use, principles of operation, design characteristics, coil configuration, treatment parameters, and electrical stimulation characteristics.

The subject device has the same intended use and similar fundamental technological characteristics as the identified predicates, including target anatomy, stimulation modality, coil configuration, stimulation waveform, stimulation output, and performance characteristics. The difference relevant to this submission is the inclusion of accelerated protocol scheduling, enabling multiple sessions per day while maintaining stimulation parameters and total course exposure within ranges supported by predicate devices and clinical literature.

The primary predicate (K220177) includes individualized fcMRI-based treatment planning as part of its clinical workflow. The subject device does not rely on an individualized fcMRI targeting algorithm; it uses standard left dorsolateral prefrontal cortex (L-DLPFC) targeting methods, such as Beam F3, 5.5 cm coil placement or via MRI-guided neuro navigation, consistent with the secondary predicate and with published MagVenture clinical evidence. This difference is a target-localization workflow difference and does not change the device's stimulation delivery, coil configuration, treatment scheduling logic, pulse characteristics, or energy-delivery characteristics. Therefore, it does not raise different questions of safety or effectiveness.

Published clinical studies using MagVenture systems with figure-of-eight coils support that accelerated TMS protocols can produce clinically meaningful antidepressant outcomes using standard scalp-based targeting methods without individualized neuro navigational targeting. The evidence includes direct comparisons of accelerated and standard once-daily treatment schedules as well as sham-controlled accelerated iTBS evidence.

Collectively, these clinical data directly address the targeting question raised by the primary predicate comparison. They show that clinically meaningful antidepressant outcomes can be obtained with accelerated rTMS and iTBS protocols delivered with MagVenture figure-of-eight coil technology using standard scalp-based targeting methods. These outcomes were achieved without individualized fcMRI-guided target selection or neuro navigational targeting in the highlighted standard-targeting studies.

This conclusion is further supported by Terao and Kodama (2025), who evaluated personalized MRI- and EEG-guided targeting approaches in comparison with fixed targeting methods. Their systematic review and meta-analysis found no statistically significant advantage of personalized targeting over fixed targeting methods. These findings support the clinical acceptability of standard targeting methods such as Beam F3 and 5.5 cm coil placement for rTMS/iTBS treatment and support the conclusion that individualized fcMRI-based targeting is not required to achieve clinically meaningful antidepressant outcomes. Collectively, the clinical evidence therefore demonstrates that intensive protocols (up to10 sessions/day) achieve comparable clinical outcomes with standard targeting methods as with fcMRI-guided targeting.

Therefore, the subject device remains substantially equivalent to the identified predicate devices. The differences from the primary predicate relate to targeting workflow rather than magnetic stimulation delivery or fundamental technology. The subject device has the same intended use, similar technological characteristics, comparable figure-of-eight coil configuration, and accelerated treatment parameters supported by predicate clearance and clinical evidence. The addition of accelerated scheduling does not raise new or different questions of safety or effectiveness, and the available clinical evidence supports substantial equivalence with respect to safety, performance, and clinical effectiveness for accelerated TMS treatment protocols.

Table 1. Comparison of New Device and Predicate Devices

Attribute	MagVenture Accelerated TMS Therapy System *(New Device)*	Magnus Neuromodulation System *(Primary Predicate Device)*	MagVenture TMS Therapy System *(Secondary Predicate Device)*	Comparison
510(k) Number	K260189	K220177	K251119	Not applicable
Manufacturer of the system	Tonica Elektronik A/S	Magnus Medical, Inc.	Tonica Elektronik A/S	Not applicable
Product Code	OBP	OBP	OBP	Same
Indications for Use	The MagVenture TMS Therapy System is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode.	The Magnus Neuromodulation System (MNS) with SAINT Technology is intended for the delivery of SAINT neuromodulation therapy to treat major depressive disorder (MDD) in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.	The MagVenture TMS Therapy System is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode.	Same as the predicate devices
Intended use	Treatment of MDD	Treatment of MDD	Treatment of MDD	Same
Intended users	Trained clinical professionals	Trained clinical professionals	Trained clinical professionals	Same
Anatomical Site	Left dorsolateral prefrontal cortex (L-DLPFC)	Left dorsolateral prefrontal cortex (L-DLPFC)	Left dorsolateral prefrontal cortex (L-DLPFC)	Same
Principle of operation	Generation of varying and focused magnetic fields to induce electric currents in specific areas of the brain to modulate neuronal activity	Generation of varying and focused magnetic fields to induce electric currents in specific areas of the brain to modulate neuronal activity	Generation of varying and focused magnetic fields to induce electric currents in specific areas of the brain to modulate neuronal activity	Same
Target Population	Adults	Adults	Adults	Same
Clinical set ting	Inpatient and outpatient settings including physician's offices and clinics, hospitals, and general medical/surgical hospitals	Inpatient and outpatient settings including physician's offices and clinics, hospitals, and general medical/surgical hospitals	Inpatient and outpatient settings including physician's offices and clinics, hospitals, and general medical/surgical hospitals	Same

Attribute	MagVenture Accelerated TMS Therapy System *(New Device)*	Magnus Neuromodulation System *(Primary Predicate Device)*	MagVenture TMS Therapy System *(Secondary Predicate Device)*	Comparison
Device design & components	Mobile console for housing of MagPro family stimulator and electronics, built in display, system software with graphic user interface Coil for MT determination and treatment Coil fixture and positioning system Treatment chair Accessory for marking and locating treatment area Head Support System Data management system	Mobile console for housing of MagPro family stimulator and electronics, built in display, system software with graphic user interface Coil for MT determination and treatment Coil fixture and positioning system Treatment chair Accessory for marking and locating treatment area Head Support System Data management system	Mobile console for housing of MagPro family stimulator and electronics, display monitor, system software with graphic user interface Coil for MT determination and treatment Coil fixture and positioning system Treatment chair Accessory for marking and locating treatment area Head Support System Data management system	Same
Biocompatibility	Patient-contacting device components use standard materials compliant with ISO 10993-1 that are commonly used in consumer products and medical device applications	Patient-contacting device components use standard materials compliant with ISO 10993-1 that are commonly used in consumer products and medical device applications	Patient-contacting device components use standard materials compliant with ISO 10993-1 that are commonly used in consumer products and medical device applications	Same
Coil Configuration	Figure-of-eight coil, Air core Liquid cooling	Figure-of-eight coil, Air core Liquid cooling	Figure-of-eight coil, Air core Liquid cooling	Same
Electrical Safety & Electromagnetic Compatibility	Complies with IEC60601-1 and IEC60601-1-2	Complies with IEC60601-1 and IEC60601-1-2	Complies with IEC60601-1 and IEC60601-1-2	Same
Quality & Risk standards	Company complies with ISO 13485:2016 and ISO 14971:2019	Company complies with ISO 13485:2016 and ISO 14971:2019	Company complies with ISO 13485:2016 and ISO 14971:2019	Same

Table 2. Accelerated iTBS treatment, 10 sessions/day

Accelerated iTBS treatment, 10 sessions/day [Cole et al., 2022]				
Attribute	**MagVenture Accelerated TMS Therapy System** *(New Device)*	**Magnus Neuromodulation System** *(Primary Predicate Device)*	**MagVenture TMS Therapy System** *(Secondary Predicate Device)*	**Comparison**
Stimulation intensity	90% MT	90% MT	Not Applicable	Same as Primary Predicate Device
Repetition rate	50 Hz	50 Hz		
Train duration	2 sec	2 sec		
Inter-train Interval	8 sec	8 sec		
Burst pulses	3	3		
Bursts	600	600		
Interpulse interval	20 msec	20 msec		
Number of pulses/sessions	1,800	1,800		
Total treatment duration	10 min	10 min		
Sessions/day	10 sessions / day with an interval of 50 min between treatments	10 sessions / day with an interval of 50 min between treatments		
Sessions per week	50	50		
Total treatment sessions	50	50		
Total treatment pulses	90,000	90,000		
Treatment duration	5 days	5 days		

Cole et al. (2022) evaluated an accelerated iTBS protocol of ten sessions per day for five consecutive days (Stanford Neuromodulation Therapy, SNT) compared with sham stimulation in patients with treatment-resistant depression, targeting the left DLPFC using individualized fcMRI-guided neuronavigation. The reported outcome measure was MADRS. The mean percent reduction in MADRS scores four weeks after treatment was 52.5% in the active treatment group and 11.1% in the sham treatment group, with response and remission rates of 85.7% and 78.6%, respectively, in the active group compared with 26.7% and 13.3% in the sham group across the four-week follow-up period. Although SNT employed individualized fcMRI-guided targeting rather than standard scalp-based targeting methods, the large antidepressant effect size observed supports the clinical effectiveness of accelerated iTBS protocols delivering up to ten sessions per day.

Table 3. Accelerated iTBS treatment, 3 sessions/day

Accelerated iTBS treatment, 3 sessions/day [Trejo-Cruz et al., 2025; Ramos et al., 2025]				
Attribute	**MagVenture Accelerated TMS Therapy System** *(New Device)*	**Magnus Neuromodulation System** *(Primary Predicate Device)*	**MagVenture TMS Therapy System** *(Secondary Predicate Device)*	**Comparison**
Stimulation intensity	100% MT	Not Applicable	Not Applicable	Substantial equivalence established via referenced clinical performance testing. The change in number of sessions per day does not raise different questions of safety and effectiveness than the predicate.
Repetition rate	50 Hz			
Train duration	2 sec			
Inter-train Interval	8 sec			
Burst pulses	3			
Bursts	400			
Interpulse interval	20 msec			
Number of pulses/sessions	1,200			
Treatment duration	6.18 min			
Sessions/day	3 sessions / day with an interval of 30 min between treatments			
Sessions per week	15			
Total treatment sessions	45			
Total treatment pulses	54,000			
Treatment duration	15 Days			

Trejo-Cruz et al. (2025) evaluated an accelerated iTBS protocol of three sessions per day for four weeks compared with a standard once-daily iTBS protocol in patients with depressive disorder and semi-structured suicidal thinking, targeting the left DLPFC using the Beam F3 method without neuro navigation. The reported outcome measures were HADRS and MADRS. The percentage reduction in depressive symptomatology was larger for the accelerated group, with HADRS reductions of 86.88% ($p = 0.005$) and MADRS reductions of 85.26% ($p = 0.005$) at four weeks, maintained at three months, with stable or slightly improved cognition. No serious adverse events were reported, and no seizures occurred, with only mild transient headache, dizziness, and nausea observed across both groups. These values demonstrate clinically meaningful and statistically significant antidepressant outcomes in the accelerated group and support the conclusion that the accelerated schedule can achieve antidepressant effectiveness using a MagVenture figure-of-eight coil and standard Beam F3 targeting without individualized neuronavigational targeting.

Ramos et al. (2025) provides additional sham-controlled evidence for non-neuro navigated accelerated iTBS using a MagVenture MagPro R30 stimulator and Cool-B70 A/P figure-of-eight coil with Beam F3 targeting. The active accelerated protocol delivered three iTBS sessions per day and produced higher week-4 HDRS-17 response and remission rates than sham: 54.7% response and 34.0% remission for active accelerated iTBS, compared with 31.9% response and 16.0% remission for sham. The study also reported that treatment was well tolerated, with no seizures or serious stimulation-related adverse events. Although Ramos et al. used a sham comparator rather than a standard once-daily comparator, it directly supports the effectiveness and safety of accelerated iTBS delivered with a MagVenture figure-of-eight coil using standard Beam F3 targeting without individualized neuronavigational targeting.

Table 4. Accelerated iTBS treatment, 2 sessions/day

Accelerated iTBS treatment, 2 sessions/day [Barnes et al., 2023; Blumberger et al., 2021]				
Attribute	**MagVenture Accelerated TMS Therapy System** *(New Device)*	**Magnus Neuromodulation System** *(Primary Predicate Device)*	**MagVenture TMS Therapy System** *(Secondary Predicate Device)*	**Comparison**
Stimulation intensity	120% MT	Not Applicable	Not Applicable	Substantial equivalence established via referenced clinical performance testing. The change in number of sessions per day does not raise different questions of safety and effectiveness than the predicate.
Repetition rate	50 Hz			
Train duration	2 sec			
Inter-train Interval	8 sec			
Burst pulses	3			
Bursts	200			
Interpulse interval	20 msec			
Number of pulses/sessions	600			
Total treatment duration	3.3 min			
Sessions/day	2 sessions / day with an interval of 50-60 min between treatments			
Sessions per week	10			
Total treatment sessions	60			
Total treatment pulses	36,000			
Treatment duration	30 days			

Barnes et al. (2023) compared twice-daily accelerated 10 Hz rTMS with once-daily standard 10 Hz rTMS delivered to the left DLPFC using Beam F3 targeting without neuro navigation. The reported outcome measure was HAMD-17. The twice-daily accelerated group improved from a mean HAMD-17 score of 17.51 (SD 4.43) to 8.80 (SD 5.03), while the once-daily standard group improved from 19.06 (SD 4.98) to 8.92 (SD 5.71). Response and remission outcomes were essentially equivalent between the protocols: twice-daily accelerated rTMS achieved 59.6% response and 44.9% remission, compared with 59.4% response and 45.4% remission for once-daily standard rTMS. These values demonstrate that a non-neuro navigated accelerated MagVenture figure-of-eight coil protocol achieved outcomes comparable to a standard once-daily protocol.

Blumberger et al. (2021) compared a twice-daily accelerated iTBS protocol with a once-daily standard iTBS protocol delivered to the left DLPFC using MRI-guided neuronavigation in patients with treatment-resistant depression. The reported outcome measure was HRSD-17. Both groups demonstrated significant within-group reductions in HRSD-17 scores at

day 10 and day 30 ($p < 0.001$ for both), with no significant between-group differences at either timepoint. Response and remission rates at day 30 were essentially equivalent between the protocols: twice-daily accelerated iTBS achieved 44.3% response and 22.7% remission, compared with 41.1% response and 23.2% remission for once-daily standard iTBS. These values demonstrate that an accelerated twice-daily iTBS schedule achieves antidepressant outcomes comparable to a standard once-daily protocol, and support the conclusion that accelerated scheduling does not raise new or different questions of safety or effectiveness. Although this study employed MRI-guided neuronavigation rather than standard scalp-based targeting, the equivalence of outcomes between the accelerated and standard arms is directly relevant to the assessment of accelerated protocol scheduling as an independent variable.

Table 5. Accelerated rTMS treatment, 4 sessions/day

Accelerated rTMS treatment, 4 sessions/day [Pettorruso et al., 2023]				
Attribute	**MagVenture Accelerated TMS Therapy System** *(New Device)*	**Magnus Neuromodulation System** *(Primary Predicate Device)*	**MagVenture TMS Therapy System** *(Secondary Predicate Device)*	**Comparison**
Stimulation intensity	120% MT	Not Applicable	Not applicable	Substantial equivalence established via referenced clinical performance testing. The change in number of sessions per day does not raise different questions of safety and effectiveness than the predicate.
Repetition rate	10 Hz			
Train duration	4 sec			
Inter-train Interval	11 - 26 sec			
Number of pulses/sessions	3,000			
Total treatment duration	19 – 37.5 min			
Sessions/day	4			
Sessions per week	20			
Total treatment sessions	20			
Total treatment pulses	60,000			
Treatment duration	5 days			

Pettorruso et al. (2023) evaluated an accelerated rTMS protocol of four sessions per day for five consecutive days compared with intranasal esketamine in patients with treatment-resistant depression, targeting the left DLPFC using the Beam F3 method without neuro navigation. The reported outcome measure was MADRS. Response rates at one month were 50% for the accelerated rTMS group compared with 17% for the esketamine group ($p = 0.048$), with remission rates of 17% and 3%, respectively. These values demonstrate a statistically significant and clinically meaningful antidepressant advantage for the accelerated rTMS protocol at the one-month timepoint, and support the conclusion that the accelerated schedule can achieve antidepressant effectiveness using a MagVenture figure-of-eight coil and standard Beam F3 targeting without individualized neuronavigational targeting.

VII. PERFORMANCE TESTING SUMMARY

Non-Clinical Testing

Non-clinical testing was performed to validate the safety and functionality of the MagVenture aTMS Therapy System under worst-case use conditions, including high-frequency protocols delivering up to 90,000 pulses per day. Testing was conducted in accordance with applicable consensus standards and the FDA Special Controls Guidance for rTMS systems, and included:

- Thermal characterization (IEC 60601-1)
- Electrical safety and electromagnetic compatibility (IEC 60601-1, IEC 60601-1-2, TS 60601-4-2)
- Biocompatibility (ISO 10993-1)
- Risk management (ISO 14971)
- Software development lifecycle (IEC 62304)

All acceptance criteria were met. These results demonstrate that the device operates safely and effectively when delivering accelerated rTMS and iTBS protocols. The testing supports the conclusion that the MagVenture aTMS Therapy System is substantially equivalent to the predicate devices in terms of performance and safety.

Clinical Performance Data

The review was structured using PICO methodology and evaluated peer-reviewed clinical studies of accelerated rTMS and intermittent theta burst stimulation (iTBS) protocols in adult patients with Major Depressive Disorder (MDD). Searches were conducted across PubMed and Cochrane CENTRAL for the period January 2015 to September 2025.

Inclusion criteria:

- Adult MDD population
- ≥2 treatment sessions per day
- Stimulation targeting the left dorsolateral prefrontal cortex (L-DLPFC)
- Full-text availability with sample size ≥20

Fourteen studies using MagVenture devices (Table 2) were identified, along with additional investigations using comparable FDA-cleared TMS systems. Studies included randomized controlled trials, open-label studies, and retrospective cohorts. Results consistently demonstrated:

- Clinically meaningful reductions in depressive symptoms across all study types
- Comparable response and remission rates to standard once-daily TMS protocols

- Favorable safety profiles, with most adverse events being mild and transient (e.g., headache, stimulation-site discomfort, fatigue)
- No clinically significant increase in adverse events with increased treatment frequency

These findings confirm that accelerated rTMS and iTBS protocols do not raise new or different questions of safety or effectiveness. The subject device's proposed protocol parameters (2–4 rTMS sessions/day, 2–10 iTBS sessions/day) fall within the cleared range of the primary predicate (Magnus Neuromodulation System, K220177), which is FDA-authorized for up to 10 sessions per day.

Therefore, the proposed labeling expansion to include accelerated scheduling is fully supported by both clinical evidence and regulatory precedent.

VIII. LABELING

The labeling of the MagVenture aTMS Therapy System is comparable to that of the predicate devices. Labeling changes are limited to protocol scheduling and no changes to indications, warnings, contraindications, or operator instructions were made.

IX. CONCLUSION

The MagVenture aTMS Therapy System is substantially equivalent to the identified predicate devices. The inclusion of accelerated protocol scheduling does not raise new or different questions of safety or effectiveness. Non-clinical testing and a robust systematic clinical literature review confirm that the device performs as intended and is safe and effective for the proposed expanded protocol use.

Table 6. Overview of Clinical Data for the MagVenture TMS Therapy System

<table>
<tr><th>Reference</th><th>Number of patients, study design</th><th>Age (mean ± sd, years)/ Diagnosis</th><th>rTMS protocol: stimulation pattern frequency, and intensity / number of pulses per session / number of sessions per day (intersession interval (ISI)) and timing / total number of sessions (pulses) per protocol

Targeting Method</th><th>Outcome measures</th><th>Side effects</th><th>Results</th></tr>
<tr><td>Barnes et al., 2023</td><td>N=210
inpatients; retrospective cohort (once n=101, twice n=109)</td><td>46.4 ± 16.2 (once),
46.4 ± 15.5 (twice)

Primary diagnosis of MDD</td><td><u>Twice-daily HF-rTMS protocol</u>
HF-rTMS, 10 Hz, 120% rMT / ~3000/session / 1/day up to 30 sessions or 2/day (2–6h apart)

Left DLPFC; Beam F3</td><td>HAMD-17</td><td>Dropout 35% once, 25% twice; tolerability acceptable</td><td>The primary outcome measure was treatment remission (defined as a reduction in HAMD-17 score to below or equal to 7). Treatment response was defined as a 50% reduction in HAMD-17 scores.

<u>Descriptive statistics of continuous outcome measures.</u>
<table>
<tr><td></td><td colspan="2">Twice daily rTMS</td><td colspan="2">Once daily rTMS</td></tr>
<tr><td></td><td>T1</td><td>T2</td><td>T1</td><td>T2</td></tr>
<tr><td></td><td>101</td><td>101</td><td>109</td><td>109</td></tr>
<tr><td>HAMD Mean (SD)</td><td>17.51(4.43)</td><td>8.8 (5.03)</td><td>19.06 (4.98)</td><td>8.92 (5.71)</td></tr>
<tr><td>HAMD Min-Max</td><td>5-29</td><td>0-25</td><td>8-36</td><td>0-27</td></tr>
<tr><td>Remission</td><td></td><td>44.9%</td><td></td><td>45.4%</td></tr>
<tr><td>Response</td><td></td><td>59.6%</td><td></td><td>59.4%</td></tr>
</table>

Both once-daily and twice-daily 10 Hz rTMS over left DLPFC achieved similar response and remission rates, confirming non-inferiority of the accelerated (twice-daily) schedule, with the added benefit of a ~45% shorter hospital stay for the twice-daily group.

Effect size (Cohen’s d): −1.5</td></tr>
<tr><td>Blumberger et al. 2021</td><td>RCT

N=208:
Once-daily real: 105
Twice-daily real: 103</td><td>42.1 ± 11.5 (once-daily)
40.7 ± 11.1 (twice-daily)

Primary diagnosis of MDD</td><td><u>Twice-daily iTBS protocol</u>

iTBS, 100% rMT (MEP) / 600 pulses (20×2 s, ITI 8 s) / 1 double (2×600) or 2/day (ISI 54 min), 5 days/week for 2–6 weeks / 20–60 sessions (12,000–36,000 pulses)

Left DLPFC; MRI navigation; F8</td><td>HDRS-17</td><td>No serious adverse events.

Discontinuation due to intolerance: 3 (rTMS), 2 (arTMS)

No serious adverse events.

Main reported AEs: Headaches (69 (rTMS), 72 (arTMS) (p=0.56)) headaches (at least once by 13 patients); Other AEs: pain, feeling of anxiety, nausea, fatigue, vomiting,</td><td>Comparison between standard and accelerated TMS groups. The primary outcome measure was the change in HRSD-17 from baseline to day 10 of treatment while the secondary outcome measure was the change from baseline to day 30 of treatment. An overview of the results is provided in the table below:
<table>
<tr><th>Comparison</th><th>Test statistic</th><th>p-value / Δ</th></tr>
<tr><td colspan="3">HDRS change, Day 10</td></tr>
<tr><td>Between-group difference</td><td>t(80.08) = -0.16</td><td>p = 0.88</td></tr>
<tr><td>Within-group arTMS</td><td>t(60.17) = -8.86</td><td>p < 0.001; Δ = -6.66</td></tr>
<tr><td>Within-group rTMs</td><td>t(107.10) = -10.42</td><td>p < 0.001; Δ = -6.66</td></tr>
<tr><td>Between-group difference</td><td>t(38.75) = 1.02</td><td>p = 0.31</td></tr>
<tr><td colspan="3">HDRS change, Day 30</td></tr>
<tr><td>Within-group arTMS</td><td>t(26.64) = -8.96</td><td>p < 0.001; Δ = -10.52</td></tr>
<tr><td>Within-group rTMs</td><td>t(64.52) = -10.52</td><td>p < 0.001; Δ = -9.05</td></tr>
</table></td></tr>
</table>

Reference	Number of patients, study design	Age (mean ± sd, years)/ Diagnosis	rTMS protocol: stimulation pattern frequency, and intensity / number of pulses per session / number of sessions per day (intersession interval (ISI)) and timing / total number of sessions (pulses) per protocol Targeting Method	Outcome measures	Side effects	Results
					blurred vision, twitching, tinnitus migraine.	Significant HRSD-17 reductions within groups at day 10 and 30 ($p<0.001$); no between-group difference at day 10/30. Day 30 response: 41.1% (rTMS) vs 44.3% (arTMS); remission: 23.2% vs 22.7%; modest 12-week advantage for arTMS (ΔHRSD-17=2.53, p=0.015)
Cole et al. 2019	Open-label feasibility N=31	19–78 (range) Primary diagnosis of MDD	>2 sessions per day iTBS protocol iTBS, 90% rMT (MEP) / 1800 pulses (60×2 s, ITI 8 s) / 10/day (ISI 50 min), over 5 days / 50 sessions (90,000 pulses) Individualized left DLPFC (sgACC anticorrelation) via fcMRI;	MADRS	No serious AEs; fatigue and mild local discomfort; no cognitive adverse effects	Mean MADRS reduction 87.24%; remission 64.4% at week 1, and 42.9% at week 4 after end of treatment
Cole et al. 2022	RCT N=29: Real aTMS: 14 Sham aTMS: 15	49 ± 15 (real) 52 ± 16 (sham) Primary diagnosis of MDD	>2 sessions per day iTBS protocol iTBS, 90% rMT (MEP) / 1800 pulses (60×2 s, ITI 8 s) / 10/day (ISI 50 min), over 5 days / 50 sessions (90,000 pulses). Individualized left DLPFC (sgACC anticorrelation) via fcMRI	MADRS HAM-D QIDS-SR	No serious adverse events. Headache was the only side effect with incidence nearing significance vs sham (p=0.06).	Comparison between aiTMS and sham. The primary outcome: MADRS (31) score 4 weeks after treatment (week 5), normalized to baseline (week 0). Response was defined as a reduction ≥50% in MADRS score, and remission was defined as MADRS score ≤10. The mean percent reduction in intention-to-treat MADRS scores. **ariTBS (N = 14)** / **Sham (N =15)** / **Cohen's d** **MADRS week 4** Response: 64.3% / 6.7% / 1.4 Remission: 42.9% / 0% / - Mixed models showed significant effects of group, time, and group × time interaction on MADRS scores ($p<0.001$). Active treatment produced greater reductions than sham at all follow-ups (Bonferroni $p<0.05$), with consistent results for HAM-D and QIDS-SR. The effect size was large (Cohen's $d>1.4$).
Fitzgerald, 2018	RCT N=115: Standard: 57 Accelerated: 58 (66 female/49 male)	49.9 ± 13.3 (standard) 48.2 ± 14.4 (aTMS) Primary diagnosis of MDD	>2 sessions per day HF-rTMS protocol HF-rTMS, 10 Hz, 120% rMT / 3150 (standard) or 3500 (aTMS) pulses / 1 or 3/day, 5 days/week × 4 weeks (ISI 15-30 min) / 20 sessions (63,000). Left DLPFC; 6 cm rule	HDRS-17 MADRS	No serious adverse events. 3 discontinued in the accelerated group due to discomfort (2) or worsening of migraine (1) Site discomfort: Accelerated: 11 Standard: 2 (p = 0.01) Headache:	Comparison between standard and accelerated TMS groups in the change from baseline to endpoint (4 and 8 weeks). An overview of the response and remission scores from baseline to treatment end (4 and 8 weeks) is provided in the table below. Response defined as a > 50% reduction in Hamilton Depression Rating Scale (HDRS) and Montgomery Asberg Depression Rating Scale (MADRS) scores. Remission defined as a HDRS score of <10 Treatment response and remission. **arTMS (N = 58)** / **Std rTMS (N = 57)** / ***χ 2*** / ***p*** **MADRS week 4** Response: 20.3% / 29.8% / 1.4 / 0.24 Remission: 11.9% / 17.5% / 0.75 / 0.39 **MADRS week 8** Response: 23.7% / 33.3% / 1.4 / 0.25 Remission: 15.3% / 12.3% / 0.21 / 0.64

Reference	Number of patients, study design	Age (mean ± sd, years)/ Diagnosis	rTMS protocol: stimulation pattern frequency, and intensity / number of pulses per session / number of sessions per day (intersession interval (ISI)) and timing / total number of sessions (pulses) per protocol Targeting Method	Outcome measures	Side effects	Results
					Accelerated:16 Standard 9 (p = 0.14).	**HDRS week 4** Response 25.4% 16.9% 0.28 0.60 Remission 29.8% 17.5% 0.01 0.93 Primary outcome: There were no significant differences in remission or response rates (p > 0.05 for all analyses) or reduction in depression scores. MADRS scores declined significantly in the accelerated group from baseline–week 1 (p<0.001), week 1–2 (p=0.01), and week 4–8 (p=0.015). In the standard group, significant reductions occurred baseline–week 1 (p<0.001), week 1–2 (p=0.021), week 2–3 (p=0.027), and week 3–4 (p<0.001).
Fitzgerald et al. 2020	RCT N=74: Standard rTMS: 38 aTMS: 36 36 females and 38 males	44.7 ± 12.2 (standard); 44.0 ± 12.2 (aTMS) Unipolar or bipolar (8%) depression; comorbidities allowed	>2 sessions per day iTBS/rTMS protocol 10 Hz standard rTMS or iTBS aTMS, 120% rMT (MEP) / 3150 pulses (75×4.2 s, ITI 25 s) standard; 600 pulses (20×2 s, ITI 8 s) aTMS / 1 or 3/day (ISI 15 min), standard 5 days/week × 4 weeks; aTMS 3 days (wk1), 2 (wk2), 1 (wks 3–4) / 20 (63,000) standard; 21 (12,600) aTMS Left DLPFC; Beam F3	MADRS	No serious adverse events. Headache: aiTBS 12, standard 7 (p>0.05); scalp pain/discomfort: TBS 4, standard 6	Comparison between standard and accelerated TMS groups. The primary outcome measure was the change in MADRS from baseline to end of weeks 1, 2, 3, 4 and 8. Response defined as a >50% reduction in Montgomery Asberg Depression Rating Scale (MADRS) scores. Remission defined as MADRS score of <11. Treatment response and remission. **arTMS (N = 36)** **Std rTMS (N = 38)** χ^2 p **MADRS week 4** Response 27.8% 26.3% 0.02 0.89 Remission 8.3% 13.2% 0.45 0.50 **MADRS week 8** Response 19.4% 28.9% 0.91 0.34 Remission 8.3% 13.2% 0.45 0.05 MADRS scores improved significantly over time (p<0.001), with reductions from baseline to weeks 1, 2, 3, and 4. There was no effect of treatment group (p=0.21) and no time × group interaction (p=0.96), indicating similar improvement across both groups.
Goodman et al., 2024	Single-arm open-label extended-course aiTBS (ECT alternative) N=155 completers	43.6 ± 14.3 Primary diagnosis of severe ECT-indicated MDD	>2 sessions per day iTBS protocol Acute: 8/day (≥50 min ISI) up to 10 days (≤80 sessions), 600/session at 110% rMT; Taper: 2 days/week ×2 weeks then 1 day/week ×2 weeks (48 sessions); Relapse prevention with rescue days; max ~128 sessions (~76,800 pulses) Left DLPFC; modified Beam F3	HRSD-24	Average pain 2.0 ± 1.9; headache 38.4%, dizziness 7.6%, nausea 7.0%, anxiety/agitation/panic 4.1%; two suicide intent/attempts; two discontinued; no seizures	HRSD-24 change: acute 8.4 (response 25.2%, remission 16.1%); taper response 49.6%, remission 34.8%; relapse prevention 60.1% reduction; 43% drop in ECT referrals Effect size (Cohen's d): 1.02 (acute), 1.29 (tapering), 1.93 (relapse prevention) The Goodman et al. (2024) study included a high-risk population of patients referred to for ECT during the COVID-19 pandemic. While two suicide attempts were reported, these events were not attributed to TMS therapy and reflect the elevated baseline risk of suicidality in this population.
Massé-Leblanc et al., 2024	Retrospective chart review	47.7 ± 14.0	>2 sessions per day HF-rTMS protocol	MADRS	Headache 37.1%, site pain 32.2%, fatigue 22.4%,	MADRS 25.2→15.1 (41%); response 46.3%; remission 36.1%; BDI-II −35%; HAM-A −34.5%; BAI −12.6% Effect size (Cohen's d): 1.28

Reference	Number of patients, study design	Age (mean ± sd, years)/ Diagnosis	rTMS protocol: stimulation pattern frequency, and intensity / number of pulses per session / number of sessions per day (intersession interval (ISI)) and timing / total number of sessions (pulses) per protocol Targeting Method	Outcome measures	Side effects	Results
	Completers: N=147 (ITT 205)	Primary diagnosis of MDD: 84.4% Bipolar: 15.6%	Accelerated TMS (predominant: unilateral 20 Hz left DLPFC 46.3% or bilateral left 20 Hz + right cTBS 19.0%); ~2.7 ± 0.9 sessions/day (≥45 min ISI); mean total 32.9 ± 5.3; intensity ~112% rMT; ~2600–2800 pulses/session; total ~90,000 pulses. Left DLPFC (some bilateral); motor-threshold mapping		dizziness 9.3%, jaw pain 6.3%, nausea 6.3%; no serious AEs; 25.5% discontinued	
Pettorruso et al., 2023	Retrospective observational N=59: arTMS:30 ESK-NS:29	54.6 ± 11.3 Primary diagnosis of MDD	>2 sessions per day HF-rTMS protocol Accelerated HF-rTMS: 4/day × 5 days (20 total), 10 Hz, 120% rMT, 3000 pulses/session (40×4 s, ITI 26 s), ISI 55 min; total 60,000 pulses Left DLPFC; BEAM F3	MADRS	Minor: headache 13%, scalp discomfort 10%, one transient agitation episode	MADRS decreased in both groups; arTMS response 50% (1 mo) and 60% (3 mo); remission 17% (1 mo) and 40% (3 mo) arTMS arm Effect size (Cohen's d): 1.82 at 3 months
Ramos et al., 2025	RCT N=100 (active vs sham) Real aTMS: 50 Sham TMS: 50	41.7 (8.8) Primary diagnosis of MDD Comorbid anxiety included	>2 sessions per day iTBS protocol Accelerated iTBS: 3/day over 15 weekdays (45 total), 1200/session, ISI 30 min, 100% rMT; total 54,000 Left DLPFC; Beam F3	HDRS-17 MDRS	Well tolerated; scalp pain in active 17.4% vs 4.4% in sham; no (hypo)mania	Response defined as a reduction of 50% in scores on the HDRS-17 from baseline to the corresponding week. Remission defined as an HDRS-17 score≤7. The mean percent reduction in intention-to-treat HDRS-17 scores. **ariTBS (N = 50)** / **Sham (N =50)** / **Cohen's d** **HDRS-17 5 weeks post-treatment** Response 54.7% / 31.9% / 0.65 Remission 34% / 16% A triple-blind, sham-controlled RCT demonstrated that a pragmatic aTBS protocol (3 iTBS sessions/day, non-navigated, low-cost) was safe and effective for TRD, yielding a medium-to-large effect size (Cohen's d 0.29–1.00; p<0.001).
Sheline, 2024	RCT N=24: Active: 12 Sham: 12	43.3 ± 16.9 Bipolar depression	>2 sessions per day iTBS protocol aiTBS: 10/day × 5 days, ~1 h ISI, 18,000/day at 90% rMT; total 90,000 Individualized left DLPFC by rs-fMRI (Cash cluster, e-field); Brainsight;	MADRS HAMD	Adverse events included headache (active group, 5 [42 %] of 12; sham group, 2 [17%] of 12) and dizziness (active group, 1 [8%] of 12; sham group, 0 [0%] of 12).	Response was defined as a ≥ 50% reduction in MADRS score and remission was defined as MADRS score ≤ 10. The mean percent reduction in MADRS scores. **ariTBS (N = 12)** / **Sham (N =12)** / **Cohen's d** **MADRS immediately post-treatment** Response 67% / 8% / ≈ 1.66 Remission 50% / 0% / - **4 weeks post-treatment**

Reference	Number of patients, study design	Age (mean ± sd, years)/ Diagnosis	rTMS protocol: stimulation pattern frequency, and intensity / number of pulses per session / number of sessions per day (intersession interval (ISI)) and timing / total number of sessions (pulses) per protocol Targeting Method	Outcome measures	Side effects	Results
					No serious AE	Response 92% 8% ≈ 2.14 Remission 75% 8% In this randomized clinical trial, aiTBS was more effective than sham stimulation for depressive symptom reduction in patients with treatment-resistant BD.
Tan et al., 2025	Open-label pilot N=38 enrolled	31.8 ± 9.5 Primary diagnosis of MDD	>2 sessions per day HF-rTMS protocol Accelerated rTMS: 5 Hz left DLPFC, 4/day × 5 days, 3000/session at 120% rMT; ISI 50 min; 12,000/day; MagPro X100. Second course: same vs 1 Hz right DLPFC; total 60,000 pulses Left DLPFC (F3) initial; right DLPFC (F4) if switched.	MADRS	Well tolerated; no serious AEs	MADRS 30.1 ± 7.0 → 25.2 ± 9.6 post; 23.6 ± 10 at 2 weeks ($p<0.01$). Response 7% post and 10% at 2 weeks; second-course response 15.8% post and 18.8% at 2 weeks; no benefit from switching to 1 Hz
Trejo-Cruz et al., 2025	RCT pilot Once n=11 3 sessions n=12	38.00 ± 12.05 41.25 ± 10.25 Primary diagnosis of MDD	>2 sessions per day iTBS protocol aiTBS: 3/day × 5 days, 600/session at 90% rMT; ISI ~10 min; total ~36,000; Left DLPFC Beam F3	MADRS HADRS	No serious AEs; mild transient headache/dizziness, nausea; no seizures	Percentage reduction in depressive symptomatology was larger for the accelerated group with HADRS (86.88%-p = 0.005) and MADRS (85.26%-p = 0.005).
Wilkening et al., 2022	RCT crossover: N=81: Real aTMS: 40 Sham aTMS: 41 34 females and 47 males	35.6 ± 13.0 Primary diagnosis of MDD Comorbidities allowed	>2 sessions per day iTBS protocol iTBS, 110% rMT (MEP) / 1800 pulses (60×2 s, ITI 8 s) / 4/day (ISI 20–30 min), over 5 days / 20 sessions (36,000 pulses). Left DLPFC; Beam F3 or individualized	MADRS HAMD BDI-II	No serious side effects of iTBS therapy were observed (56.18% scalp pain, 52.47% headache, 30.25% neck pain, 20.99% scalp irritation).	**MADRS (primary):** Active iTBS reduced scores by ~30% vs ~20% for sham, with a significant group difference (p=0.03, d≈0.69). **BDI-II:** Both groups improved significantly; active ~28% vs sham ~21%. No significant between-group difference (d≈0.4). **QIDS-SR16:** Both groups improved; active ~33% vs sham ~27%. No significant between-group difference (d≈0.3).

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