August 11, 2025

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

Re: K251125
Trade/Device Name: MagVenture TMS Therapy System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: July 11, 2025
Received: July 14, 2025

Dear Dr. 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 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

Digitally signed by PAMELA D. SCOTT -S
Date: 2025.08.11 19:31:09 -04'00'

Pamela D. 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.	K251125

Please provide the device trade name(s).

MagVenture TMS Therapy System

Please provide your Indications for Use below.

MagVenture TMS Therapy System is indicated as an adjunct for the treatment of Major Depressive Disorder in adolescent patients (age 15-21).

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

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Tonica Elektronik A/S

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: August 8, 2025

I. SUBMITTER

Tonica Elektronik A/S
Lucernemarken 15
DK-3520 Farum, Denmark
Tel: +45 4499 1544

Primary Contact: Kirstine Klitgaard Schou, Ph.D.
Senior Medical Affairs Specialist
Phone: +45 6114 6675
E-mail: kks@magventure.com

Secondary Contact: Jan Kjøller
Head of Regulatory Affairs
Phone: +45 2489 9976
E-mail: jk@magventure.com

II. DEVICE

Device Trade Name: MagVenture TMS Therapy System
Classification Names: Repetitive transcranial magnetic stimulation system
Regulation: 21 CFR 882.5805
Regulatory Class: Class II
Device Panel: Neurology
Product Code: OBP

III. PRIMARY PREDICATE DEVICE

Predicate Manufacturer: Neuronetics Inc.
Predicate Trade Name: NeuroStar Advanced Therapy System
Predicate 510(k): K231926
Predicate Regulation: 21 CFR 882.5805
Predicate Regulatory Class: Class II
Predicate Device Panel: Neurology
Predicate Product Code: OBP

IV. PREDICATE DEVICE

Predicate Manufacturer:	Tonica Elektronik A/S
Predicate Trade Name:	MagVita TMS Therapy System
Predicate 510(k):	K150641, K170114, K171481, K171967, K172667, K173620
Predicate Regulation:	21 CFR 882.5805
Predicate Regulatory Class:	Class II
Predicate Device Panel:	Neurology
Predicate Product Code:	OBP

V. DEVICE DESCRIPTION

The MagVenture TMS 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.
The pulses 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 TMS 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, Cool D-B80
- Accessories:
    - Trolley with mounting for super flexible arm and coil holder arrangement)
    - Patient head fixation
    - 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 Pillow Case for patient head fixation (Optional)
    - Treatment Chair (Optional)

- Coil Hub (Optional)
- MagVenture TMS Atlas Neuro Navigation System (Optional)

Except for the Beam F3 marking plate, all components have previously received FDA clearance. The MagVenture TMS Therapy System and its technological characteristics remain equivalent to those cleared under K150641, K170114, K171481, K171967, K172667, K173620.

This submission introduces the following modifications:

- Expanded Indications: MagVenture TMS Therapy System is indicated as an adjunct for the treatment of Major Depressive Disorder (MDD) in adolescent patients (age 15-21)
- Coil Approval Expansion: Inclusion of Cool D-B80 for MDD in adolescent patients (age 15-21).
- Beam F3 Marking Method: Introduces the Beam F3 marking plate as an alternative to the standard 5.5 cm method for coil positioning in the dorsolateral prefrontal cortex (DLPFC).

Apart from the modifications outlined above, the core design, fundamental operating principles, and safety characteristics remain substantially equivalent to the previously cleared MagVenture TMS Therapy System.

VI. INDICATIONS FOR USE STATEMENT

MagVenture TMS Therapy System is indicated as an adjunct for the treatment of Major Depressive Disorder (MDD) in adolescent patients (age 15-21).

VII. SUBSTANTIAL EQUIVALENCE DISCUSSION

The following table compares the MagVenture TMS Therapy System to the (primary) predicate device with respect to indications for use, and technological characteristics including principles of operation, design and output stimulation parameters, and forms the basis for the substantial equivalence determination.

The new device is substantially equivalent to the primary predicate device (K231926). They have the same intended use and indications for use. Both devices use the same principles of operation to apply TMS treatment at a defined intensity as repetitive pulse trains delivered as brief rapidly alternating magnetic fields to induce electrical currents to the prefrontal cortex. They have substantially equivalent technological characteristics. Both devices represent integrated systems of components including TMS stimulator with software, electromagnetic figure-of-8-coil for MT determination and treatment, coil fixture and positioning system and head support system. The operational procedures including system setup, patient preparations, motor threshold

determination, coil positioning and patient treatment with predefined treatment stimulation settings are substantially equivalent. Devices target the identical anatomical area of the brain. Minor identified differences in system components and output stimulation paraments do not raise different questions of safety and effectiveness than the primary predicate.

Substantial equivalence between the MagVenture TMS Therapy System and NeuroStar Advanced Therapy System, having identical technological characteristics as described for the respective systems in this 510(k) submission, has previously been demonstrated via 510(k) clearances K150641 and K171481 covered by the predicate device (MagVita TMS Therapy System).

The new device is substantially equivalent to the predicate device. They have the same intended use and identical technological characteristics. The predicate device previously obtained FDA clearance for the treatment of major depressive disorder (MDD) in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode (K150641, K170114, K171481, K171967, K172667, K173620).

Tonica Elektronik A/S

Table-1 Comparison of Technological Characteristics for Major Depressive Disorder (MDD) in adolescent patients (age 15-21) and (Primary) Predicate Device

Attribute	MagVenture TMS Therapy System (New device)	NeuroStar Advanced Therapy System (Primary predicate device)	MagVita TMS Therapy System (Predicate device)	Comparison
510(k) Number	K251125	K231926	K150641, K170114, K171481, K171967, K172667, K173620	Not applicable
Manufacturer of the system	Tonica Elektronik A/S	Neuronetics, Inc.	Tonica Elektronik A/S	Not applicable
Product Code	OBP	OBP	OBP	Same
Indications for Use	MagVenture TMS Therapy System is indicated as an adjunct for the treatment of Major Depressive Disorder (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 (age 15-21)	MagVita TMS Therapy System is indicated 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	Same intended use and indications for use as primary predicate. Same intended use as predicate.
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	Adolescent patients aged 15-21 years	Adolescent patients aged 15-21 years	Adults	Same as primary predicate. Substantial equivalent to predicate

Attribute	MagVenture TMS Therapy System (New device)	NeuroStar Advanced Therapy System (Primary predicate device)	MagVita TMS Therapy System (Predicate device)	Comparison
Clinical setting	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
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 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	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	Substantially equivalent to primary predicate. Same as predicate.
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 Ferromagnetic Core Air cooling	Figure-of-eight coil Air core Liquid cooling	Substantial equivalent to primary predicate. Same as predicate.

Attribute	MagVenture TMS Therapy System (New device)	NeuroStar Advanced Therapy System (Primary predicate device)	MagVita TMS Therapy System (Predicate device)	Comparison
Performance	**Waveforms:** Biphasic **Frequency:** 0.1 - 30 PPS or 0.1 - 100 pulses, depending on model **Preset range of % MT:** 0 - 140% **Amplitude Range:** 0 - 1.7 SMT (80 - 120% MT) (Standard & iTBS treatment) **Pulse width:** 290 µs (± 5%)	**Waveforms:** Biphasic **Frequency:** 1 - 30 PPS. For MT determination: 0.1 - 0.3 PPS **Preset range of % MT:** 25 - 140% **Amplitude Range:** Standard treatment: 0.22 to 2.08 SMT; iTBS treatment: 0.22 to 1.9 SMT **Pulse width:** 185 µs (±10%)	**Waveforms:** Biphasic **Frequency:** 0.1 - 30 PPS or 0.1 - 100 pulses, depending on model **Preset range of % MT:** 0 - 140% **Amplitude Range:** 0 - 1.7 SMT (80 - 120% MT) (Standard & iTBS treatment) **Pulse width:** 290 µs (± 5%)	Same
Treatment Protocol	**Standard Protocol**			
Stimulation intensity	120% MT	120% MT	120% MT	Same
Repetition rate	10 Hz	10 Hz	10 Hz	
Train duration	4 sec	4 sec	4 sec	
Inter-train Interval	11 - 26 sec	As low as 11 sec	11 - 26 sec	
Number of pulses/session	3000	3000	3000	
Total treatment duration	19 - 37.5 min	As low as 18.75 min	19 - 37.5 min	
Treatment Protocol	**iTBS#**			
Stimulation intensity	120% MT	80-120% MT	120% MT	Substantially equivalent to primary predicate. Same as predicate
Repetition rate	50 Hz	50 Hz	50 Hz	
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	
Interpulse interval	20 msec	20 msec	20 msec	

Attribute	MagVenture TMS Therapy System (New device)	NeuroStar Advanced Therapy System (Primary predicate device)	MagVita TMS Therapy System (Predicate device)	Comparison
Number of trains	20	20	20	
Pulses per session	600	600	600	
Total treatment duration	3 min and 9 sec	3 min and 20 sec	3 min and 9 sec	
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

VIII. PERFORMANCE TESTING SUMMARY

Non-Clinical Performance Testing and Performance Standards

The MagVenture TMS Therapy System has been tested and complies with the following recognized electrical safety and performance standards:

- IEC 60601-1: General safety and essential performance requirements.
- IEC 60601-1-2: Electromagnetic compatibility compliance.
- IEC TR 60601-4-2: Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- ISO 13485:2016 & ISO 14971:2019: Quality and risk management compliance.

Additionally, computational modeling (SimNIBS v4.0.1) has been used to compare the electric field strength of the MagVenture coils against the predicate device.

Clinical Performance Data

The primary predicate device (K231926) has been shown to be clinically safe and effective as an adjunct for the treatment of Major Depressive Disorder (MDD) in adolescent patients aged 15-21 years.

The new device is substantially equivalent to the primary predicate device. Since the proposed device is sufficiently similar to the NeuroStar TMS Therapy System in terms of indications, device specifications and energy output, the omission of clinical testing is justified by the SE determination and reliance on prior performance testing per indicated relevant consensus standards and FDA Special Controls Guidance for rTMS as performed for the predicate MagVita TMS Therapy System.

To further support the substantial equivalence determination for the new device, however, the applicant performed a systematic clinical literature review based on PICO principles to evaluate the safety and effectiveness of TMS for the treatment of MDD in adolescent patients (15-21 years).

Searches were performed using PubMed, PubMed Central (PMC) and Cochrane Central Register of Controlled Trials databases up to April 30, 2024. Searches included combinations of the following terms: [Transcranial magnetic stimulation], [(r)TMS], [depression], [major depressive disorder], [adolescent], [young adult], [child(ren)], [teenager], [MagVita TMS Therapy], [NeuroStar Advanced Therapy], [MagVenture], [Neuronetics], [Tonica Elektronik], [antidepressant] and [antidepressant therapy]. Defined clinical paper selection criteria included:

- Prospective, retrospective, controlled or non-controlled clinical trials or case series covering ≥ 6 patients addressing depression related endpoints
- Adolescents (15-21 years), male or female
- Patients with clinical diagnosis of major depressive disorder

- MagVita/MagVenture TMS System, NeuroStar TMS System or comparable TMS system with Figure-of-eight-coil
- Anatomical location: Left-DLPFC
- rTMS or intermittent Theta Burst Stimulation (iTBS) treatment protocol
- Full text English paper

The systemic review resulted in the selection of a total of five (5) prospective randomized controlled clinical trials (Pan et al., 2020; Chen et al., 2022; Croarkin et al., 2021; Zhao et al., 2023; Zhang M et al., 2024) in which TMS was used as an adjunct for the treatment of MDD, ten (10) open label, single arm studies (Wall, 2011, 2016; Dhami et al., 2019; Zhang T et al., 2019; MacMaster et al., 2019; Sphere et al., 2021; Croarkin et al., 2018, 2016; Lu et al., 2023; Zhang L et al., 2020), one (1) prospective comparative study (Gordon et al, 2022), one (1) retrospective comparative study (Rosenich et al., 2019) and two (2) retrospective case series (Croarkin et al., 2024; Nakano et al., 2023). They cover a total of 447 adolescent patients in which TMS was applied for the treatment of MDD.

The review further identified ten (10) systematic literature reviews (Sigrist et al. 2022; Oberman et al., 2021; Hett et al., 2021; Magavi et al., 2017; Cao et al., 2023; Bejenaru et al., 2022; Majumder et al., 2021; Qiu et al., 2023; Sun et al., 2023; Donaldson et al., 2014). Five (5) of these reviews included a meta-analysis (Sigrist et al. 2022; Cao et al., 2023; Majumder et al., 2021; Qiu et al., 2023; Sun et al., 2023).

Clinical data on the proposed MagVenture TMS Therapy System is reported by the studies of Zhang T et., 2019 (N=42), Rosenich et al., 2019 (N=15), Croarkin et al., 2024 (N=58), Zhang L et al., 2020 (N=13), Nakano et al., 2023 (N=6) and Gordon et al., (N=14), covering a total of 148 adolescent patients (Table 2). These studies further indicate the safety and effectiveness of the new TMS device for the treatment of MDD in adolescent patients aged 15-21 years.

The literature review indicates that TMS is effective as an adjunct for the treatment of MDD in adolescents aged 15-21 years. All studies concluded that TMS is well tolerated and safe for this patient population. Side effects of TMS treatment are similar to those observed in adults. They are typically mild and transient and include headaches, skull discomfort, musculoskeletal discomfort, neck pain, twitching/tingling, mood changes, fatigue, nausea, dizziness anxiety, tingling and tinnitus. No serious adverse events were reported.
The systematic clinical literature review, covering clinical data from the proposed device and substantially equivalent devices, therefore confirms that the use of TMS therapy as an adjunct for the treatment of MDD in adolescent patients aged 15-21 years is safe and effective. Clinical data further demonstrates substantially equivalent treatment effect of TMS therapy as an adjunct to antidepressant therapy over antidepressant therapy alone in reducing depression in adolescents that is consistent within and across the studies.

IX. PERFORMANCE TESTING SUMMARY

The proposed MagVenture TMS Therapy System is substantially equivalent to the primary predicate device. They have the same intended use and indications for use and the same or similar technological characteristics. Identified differences do not raise new or different questions of safety and effectiveness.

Non-clinical performance testing per relevant consensus standards and FDA Special Controls Guidance Document for rTMS System as performed for the predicate device support the conclusion that the performance and safety characteristics of the MagVenture TMS Therapy System are substantially equivalent to the primary predicate device.

The safety and effectiveness of the new device and the substantial equivalence determination is further supported by clinical data retrieved from systematic literature review using defined inclusion criteria and covering the use of the subject device, primary predicate device and comparable devices for the treatment of MDD in adolescent patients aged 15-21 year.

Table-2. Overview of Clinical Data for the MagVenture TMS Therapy System

Reference	Study Design and Protocol	Patients	N	Outcome Measures	Clinical effectiveness	Clinical safety	HAMD Effect Size Hedges' g *
Zhang T et al., 2019	Design: Open label Groups: rTMS applied in Adolescents, Adults, and Older Adults TMS Device: MagVenture TMS System, Figure-of-8-coil Protocol: L-DLPFC 120% MT; 10 Hz ITI: 12s 2,400 pulses; 20 sessions, 4 wks	Patients with mood and anxiety disorders. Age (years) Adolescents: M = 14.6 S = 2.0 R = 10- 17 Gender (M/F): 13/29	Adolesc: N = 42 Adult: N = 75	HAM-D	**Results:** An overview of the mean depression scores from baseline to 2 weeks and treatment end (4 weeks) is provided in the table below: **HAMD** — **Active TMS (N = 42)** — **P** **Baseline mean scores** — **16.4 ± 5.1** **2 wk mean scores** — **6.9 ± 3.4** — **<0.001** **4 wk mean scores** — **4.3 ± 2.1** ***(N=19)*** — **<0.001** While all age groups demonstrated improvement in depression symptoms following rTMS therapy, subjects in the adolescent group demonstrated statistically significant superior outcomes to those of subjects in each of the adult and older groups at both 2-week and 4-week assessments. Response (≥50% decrease in HAMD) and remission (HAMD<7) rate for adolescents: 2-week response rate: 50% 2-week remission rate: 54.3% 4-week response rate:100% 4-week remission rate: 91.3% **Conclusion:** Add-on rTMS is feasible, tolerable, effective and more applicable to adolescents with mood or anxiety disorders.	No serious adverse events reported AEs reported included transient mild headache and musculoskeletal discomfort	5.49 (@ wk2) 95% CI: [4.275, 6.695] Large effect size 3.86 (@ wk4) 95% CI: [2.561, 5.164] Large effect size
Rosenich et al., 2019	Design: Retrospective, comparative Group: rTMS (MagVenture TMS System, Figure-of-8-coil; Neuro-MS/D TMS System, Figure-of-8-coil) Protocol: Right unilateral (n=8) or bilateral (n=4) DLPFC 110% MT; 1 Hz (R-DLPFC) and/or 10 Hz (L-DLPFC) 900-2,400 pulses 18 sessions, 3/wk for 6 wks.	Patients with treatment resistant MDD Age (years): M = 20.69 S = 2.55 R = 17-25 Gender (M/F): 8/7	N = 15	HAM-D MADRS Zung Self-Rating Depression Scale	**Results:** An overview of the mean depression scores from baseline to treatment end (3 weeks) is provided in the table below: **Active rTMS (N = 15)** — **F** — **P** **HAMD** **Baseline mean scores** — **19.20 ± 5.16** **6 wk mean scores** — **11.93 ± 6.22** — **4.71** — **<0.0001** **MADRS** **Baseline mean scores** — **30.23 ± 5.57** **6 wk mean scores** — **20.80 ± 9.18** — **3.96** — **<0.01** **Zung** **Baseline mean scores** — **58.47 ± 6.23** **6 wk mean scores** — **49.03 ± 9.32** — **4.13** — **<0.01** Three measures of depression demonstrated statistically significant improvements in post-treatment scores for 15 adolescents with MDD treated with TMS. Furthermore, the findings were consistent with those for a group of adult patients with MDD who were treated at the same facility using the same treatment protocol. **Conclusion:** Results indicate that TMS therapy is equally effective on adolescents as it is on adults when used as an adjunctive therapy to antidepressants.	No serious adverse events reported AEs included mild and transient side effects such as discomfort at the treatment site, headache, and tiredness following treatment	-6.48 95% CI: [-8.854, -4.115] Large effect size
Croarkin et al., 2024	Design: Retrospective case series TMS Device: MagVenture TMS	Diagnosed MDD Age (years): M = 15.8 S = 1.1 R = 12-17	N = 58	PHQ-9 GAD-7	**Results:** An overview of the mean depression and anxiety scores PHQ-9 and GAD-7, respectively, from baseline to 8 weeks is provided in the table below: Overall, 32/57 treatment-completers (56.1%) met response criteria and 20/57 (35.1%) met remission criteria. Overall PHQ-9 scores improved by an average of 48.7%, from 15.2 ± SD6.1 to 7.8 ± SD6.1, indicating a large effect size (Cohen's d = 1.10).	No serious adverse events observed. There were no seizures, suicide attempts, completed suicides, or other serious adverse events.	Not applicable

Reference	Study Design and Protocol	Patients	N	Outcome Measures	Clinical effectiveness	Clinical safety	HAMD Effect Size Hedges' g *
	Therapy System; Figure-of-8-coil Protocol: R-DLPFC: 120% MT; 1Hz 60 s on/30 s off, 6 trains, 360 pulses total L-DLPFC: 120% MT; 20 Hz 2 s on/4 s off, 30 trains, 1200 pulses total Daily sessions (week days) total of 36 sessions				**Conclusion:** The authors indicated that the observations from the retrospective case series suggest that a bilateral 1 Hz right/20 Hz left DLPFC protocol is safe, tolerable, and effective for both depressive symptoms and anxiety, with large effect sizes seen in this sample of adolescents. **Active rTMS (N = 58)** / **Cohen's d** **PHQ-9** **Baseline mean scores** 15.2 ± 6.08 - **8 wk mean scores** 7.8 ± 6.05 -1.10 **GAD-7** **Baseline mean scores** 11.8 ± 5.85 - **8 wk mean scores** 5.9 ± 5.2 -0.94	Safety and tolerability were strong, with 57/59 patients completing at least 30 sessions and no dropouts due to adverse effects.	
Zhang L et al., 2020	Design: Open label Groups: rTMS applied in Adolescents, Adults, and Older Adults TMS Device: MagVenture TMS System; Figure-of-8-coil Protocol: L-DLPFC: 120% MT; 10 Hz ITI: 12s; 30 pulses per train 80 stimulation trains per session 20 sessions, 4 wks R-DLPFC: 120% MT; 1 Hz ITI: 12s; 30 pulses per train 80 stimulation trains per session 20 sessions, 4 wks	Patients with depression and anxiety symptoms Age (years): M = 15.24 S = 1.61	N = 13	HAMD-17	**Results:** An overview of the mean depression scores from baseline to 4 weeks is provided in the table below: **Active rTMS (N = 13)** / **P** **HAMD** **Baseline mean scores** 14.31 ± 5.60 **4 wk mean scores** 3.23 ± 1.74 **<0.001** **Conclusion:** Results indicate that rTMS is a safety and effective add-on therapy for the treatment of depression in adolescents.	No serious adverse events reported. AE reported was dizziness	2.69 95% CI: [1.536, 3.839] Large effect size
Nakano et al., 2023	Design: Case series TMS Device: MagVenture TMS System, Figure-of-8-coil	Patients diagnosed with MDD Age (years): R = 16-18 Gender (M/F) 5/1	N = 6	PHQ-9	**Results:** Remission: 50% (3/6) (PHQ-9 score < 5) Response: 33% (2/6) (≥ 50% reduction in PHQ-9 scores) The Standard Mean Difference (SMD) for PHQ-9 scores was 1.6 at 1-month posttreatment. **Conclusion:** These findings support the safe, clinical use of accelerated iTBS as an adjunct for the treatment of MDD in adolescents	No serious adverse events reported. All patients tolerated treatment well. Reported AEs included headache, minor eye strain, 'abdominal twitching', irritability	Not applicable

Reference	Study Design and Protocol	Patients	N	Outcome Measures	Clinical effectiveness	Clinical safety	HAMD Effect Size Hedges' g *
	Protocol: L-DLPFC: iTBS 120% MT 1800 pulses Mean total sessions: 44 up to 1 month						
Gordon et al., 2022	Design: Prospective randomized trial TMS Device: MagVenture TMS System Protocol: 120% MT; 20 treatments in 4 weeks L-DLPFC: high frequency rTMS; 10 Hz 45 trains of 4 sec; ITT: 26 sec; 1800 pulses/day R- DLPFC: low frequency rTMS; 1 Hz 1 train of 30 min; 1800 pulses per day	Diagnosed MDD Age (years): M = 16.5 S = 1.16 Gender (M/F): 4/10	N = 14	CDRS-R	**Results:** An overview of the response rates based on CDRS-R scores after 20 treatments and 1-month follow-up is provided in the table below: **Active iTMS (N = 14)** **20 treatments** **Partial response** **7.1% (1/14)** **Response** **0% (0/14)** **1-month** **Partial response** **28.6% (4/14)** **Response** **14.2% (2/14)** *Partial response (25-50% reduction in CDRS-R); response (≥50 % score reduction in CDRS-R)* CDRS-R score changes from baseline were -14.99 after 20 treatments (P<0.001; [95% CI: -19.77, -10.20]) and -17.62 after 1-month follow-up (P<0.001; [95% CI: -22.54, -12.70]). CDRS-R scores improved significantly across the 20 rTMS treatments, with peak response at 1-month follow-up. Two (14%) adolescents had ≥ 50% score improvement and a further four (29%) demonstrated partial response (between 25 and 50% reduction) by 1-month follow-up. Treatment gains were sustained at 6-month follow-up. There was no significant difference in efficacy between left- and right-sided treatment **Conclusion:** It is concluded that adolescents with MDD benefited from rTMS	No serious adverse events reported Treatment was well-tolerated Most reported side-effects during treatment were lethargy and drowsiness Headaches were reported by nine participants	Not applicable

Significance values for P are expressed in comparison to baseline values, or to control group in case of controlled studies;
Beck Scale for Suicide Ideation (BSI); Hamilton Depression Rating Scale (HAMD); Montgomery-Åsberg Depression Rating Scale (MADRS); Wisconsin Card Sorting Test (WCST) Continuous Performance Test (CPT); Stroop Color-Word Test (SCWT); Children's Depression Rating Scale-Revised (CDRS-R)
Quick Inventory of Depressive Symptomatology–- Adolescent (17 Item) – Self Report (QIDS- A17-SR); Clinical Global Impression's Scale – Severity (CGI-S)
Beck Depression Inventory (BDI); Quality of Life Enjoyment and Satisfaction Questionnaire (QLES-Q; Brief Psychiatric Rating Scale for Children (BPRS- C)
Children's Global Assessment Scale (CGAS); Suicidal Ideation Questionnaire (SIQ); Patient Health Questionnaire (PHQ-9); 7-item Generalized Anxiety Disorder scale (GAD-7); Hamilton Anxiety Scale (HAMA)

** Where Hedges' g represents an effect size Small: < 0.2; Medium: 0.5; Large: > 0.8.*