August 8, 2025

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

Re: K251119
Trade/Device Name: MagVenture TMS Therapy System
Regulation Number: 21 CFR 882.5805, 21 CFR 882.5802
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP, QCI
Dated: July 11, 2025
Received: July 14, 2025

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 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: 2025.08.08 23:01:16 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251119

Device Name
MagVenture TMS Therapy System

Indications for Use *(Describe)*
MagVenture TMS Therapy 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 have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.

The MagVenture TMS Therapy system is intended to be used 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 submitted in accordance with the requirements of 21 CFR §807.92:

Date Prepared: August 8, 2025

I. SUBMITTER

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

Device Trade Name: MagVenture TMS Therapy System
Classification Names: Repetitive transcranial magnetic stimulation system
Transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions.
Regulation: 21 CFR 882.5805, 21 CFR 882.5802
Regulatory Class: Class II
Device Panel: Neurological Therapeutic Devices
Product Classification Code: OBP, QCI

III. PREDICATE DEVICE

Predicate Manufacturer: Neuronetics
Predicate Trade Name: NeuroStar Advanced Therapy System
Predicate 510(k): K230029
Predicate Regulation: 21 CFR 882.5805, 21 CFR 882.5802
Predicate Product Code: OBP, QCI

IV. 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, K171481, K171967, K173620, K193006 for Major Depressive Disorder (MDD) and Obsessive-Compulsive Disorder (OCD) indications.

This submission introduces the following modifications:

- Expanded Indications: Includes treatment for depressive episodes and comorbid anxiety symptoms in adult patients with MDD who have not responded satisfactorily to prior antidepressant medication.
- Coil Approval Expansion: All three MagVenture treatment coils are now included for MDD, MDD w/ comorbid anxiety symptoms, depressive episodes, and OCD treatment.
- 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).

All other aspects of the device compared to the currently marketed MagVenture TMS Therapy remain unchanged.

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.

- The MagVenture TMS Therapy system is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

VI. SUBSTANTIAL EQUIVALENCE DISCUSSION

The following tables covering product codes OBP and QCI compare the MagVenture TMS Therapy System to the predicate device with respect to indications for use and intended 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 predicate device (K230029). 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 coils 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 the NeuroStar Advanced Therapy System has been previously demonstrated in prior FDA clearances for the existing indications for use (K150641, K171481). The technological characteristics of the MagVenture TMS Therapy System are unchanged in this submission from those prior clearances.

The MagVenture TMS Therapy System has 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 Technological comparison with primary predicate for MDD w/ Comorbid Anxiety Symptoms (Product Code: OBP):

Items	New device	Predicate device	Statement of equivalence
Trade Name	**MagVenture TMS Therapy System**	**NeuroStar Advanced Therapy System**	Not applicable
Manufacturer	Tonica Elektronik A/S	Neuronetics Inc.	
510(k)	K251119	K230029	
Product codes/Classification	OBP	OBP	Same
Regulation Numbers	21 CFR 882.5805	21 CFR 882.5805	Same
CLINICAL CHARACTERISTICS			
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 NeuroStar Advanced 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
Intended Use	Major Depressive Disorder (MDD) and comorbid anxiety symptoms	Major Depressive Disorder (MDD) and comorbid anxiety symptoms	Same
Clinical Settings	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
Target populations	Adult Patients	Adult Patients	Same
Treatment schedule	5 days per week for 4-6 weeks Total of 20-30 treatment sessions plus 6 taper sessions over 3 weeks	5 days per week for 4-6 weeks Total of 20-30 treatment sessions plus 6 taper sessions over 3 weeks	Same
Area of the brain to be stimulated	Left dorsolateral prefrontal cortex	Left dorsolateral prefrontal cortex	Same
TREATMENT PARAMETERS – STANDARD TREATMENT			
Magnetic Field Intensity	120% of MT	120% of MT	Same recommended treatment parameters
Repetition Rate	10 Hz	10 Hz	
Train duration	4 sec	4 sec	
Inter-train interval	11-26 sec	11-26 sec	

No of trains	75	75	
Pulses per session	3000	3000	
Session Duration	18.75-37.5 min	18.75-37.5 min	
TREATMENT PARAMETERS – THETA BURST			
Magnetic Field Intensity	120% of MT with allowable adjustments	80-120% MT with allowable adjustments	Same recommended treatment parameters
Train duration	2 sec	2 sec	
Inter-train interval	8 sec	8 sec	
Pulses per Burst	3	3	
Bursts per Second	5	5	
Inter-pulse Interval	20 ms	20 ms	
Session Duration	3.15	3.15	
Pulses Per Session	600	600	
COIL SPECIFICATIONS			
Coil type	Figure-of-eight design with dual windings and an air core.	Figure-of eight- design with a ferromagnetic core	Substantially equivalent with no new or different questions of safety or effectiveness than the predicate device.
Windings	Depending on coil variant: 2×75mm 2×97mm 2×95mm	2×70mm	Substantially equivalent with no new or different questions of safety or effectiveness than the predicate device.
Pulse Type	Biphasic	Biphasic	Same
Pulse width	290 µs (±5%)	185 µs (±10%)	Substantially equivalent with no new or different questions of safety or effectiveness than the predicate device.

Cooling	Forced liquid cooling	Air Cooled	Both methods of cooling are sufficient for the specific design.
Maximum Coil Temperature	43°C	44°C	Similar Both systems will automatically disable if this maximum temperature is reached
TECHNOLOGICAL CHARACTERISTICS			
Device components	1. Mobile console 2. System software with GUI 3. Treatment chair 4. Head support system 5. Coil positioning system standard 5.5 cm method and Beam F3 method for determining treatment location and coil positioning 6. Same coil for both MT and treatment or MT coil and treatment coil 7. Coil Fixture 8. Data Management System	1. Mobile console 2. System software with GUI 3. Treatment chair 4. Head support system 5. Coil positioning system standard 5 cm method and Beam F3 method for determining treatment location and coil positioning 6. Same Coil for both MT and treatment 7. Coil fixture 8. Data management system	Similar
Power Source	Power Supply Mobile console: 110Vac, 20A	Power Supply Mobile console: 110Vac, 20A	Same
Frequency range (Hz) at 100%	0.1-30 (MagPro R30) and 0.1-100 (MagPro X100)	1-30	Substantially equivalent with no new or different questions of safety or effectiveness than the predicate device.
Preset range of % MT	0 – 140%	25 – 140%	
Pulse train duration range (sec)	1 – 33	1 – 20	
Inter-train interval range (sec)	0.1 – 120 (±2%)	10 – 60	
Available Stimulation Intensity in terms of Standard Motor	Ranging from 0 – 2.2 SMT depending on coil capabilities	Range: 0.22 - 2.08 SMT	

Threshold (SMT) units			
Peak magnetic field strength (T) at a depth of 2cm	Ranging from 0.46 – 0.55T depending on coil capabilities.	0.5T	Substantially equivalent with no new or different questions of safety or effectiveness than the predicate device.
Peak magnetic field gradient dB/dt (kT/s) at a depth of 2cm	Ranging from 9 – 12 kT/s depending on coil capabilities	11 kT/s	
PERFORMANCE DATA			
Electrical Safety & Electromagnetic Compatibility	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	

*SE: Substantial equivalent

Table-2. Technological comparison with primary predicate for OCD (Product Code: QCI):

Items	New device	Predicate device	Statement of equivalence
Trade Name	**MagVenture TMS Therapy System**	**NeuroStar Advanced Therapy System**	Not applicable
Manufacturer	Tonica Elektronik A/S	Neuronetics Inc.	
510(k)	K251119	K230029	
Product codes/Classification	QCI	QCI	Same
Regulation Numbers	21 CFR 882.5802	21 CFR 882.5802	Same
CLINICAL CHARACTERISTICS			
Indications for use	The MagVenture TMS Therapy system is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD)	The NeuroStar Advanced Therapy System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD)	Same
Intended use	Obsessive-Compulsive Disorder	Obsessive-Compulsive Disorder	Same
Clinical Settings	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
Target populations	Adult Patients (ages 22-68)	Adult Patients (ages 22-70)	Similar. Age within ranges of predicate device.
Treatment schedule	Weeks 1-5: 1 treatment session per day for 5 days Week 6: 1 treatment session per day for 4 days Total of 29 treatment sessions	Weeks 1-5: 1 treatment session per day for 5 days Week 6: 1 treatment session per day for 4 days Total of 29 treatment sessions	Same
Area of the brain to be stimulated	Dorsomedial prefrontal cortex	Dorsomedial prefrontal cortex	Same
TREATMENT PARAMETERS			
Magnetic Field Intensity	100% of MT (Tibialis Motor Cortex)	100% of MT (leg motor cortex)	Same recommended treatment parameters
Repetition Rate	20 Hz	20 Hz	
Train duration	2 sec	2 sec	
Inter-train interval	20 sec	20 sec	
No of trains	50	50	

Pulses per session	2000	2000	
Session Duration	18.3 min	18.3 min	
COIL SPECIFICATIONS			
Coil type	Figure-of-eight design with dual windings and an air core.	Figure-of eight-design with a ferromagnetic core	Substantially equivalent with no new or different questions of safety or effectiveness than the predicate device.
Windings	Depending on coil variant: 2×75mm 2×97mm 2×95mm	2×70mm	
Pulse Type	Biphasic	Biphasic	Same
Pulse width	290 µs (±5%)	185 µs (±10%)	Substantially equivalent with no new or different questions of safety or effectiveness than the predicate device.
Cooling	Forced liquid cooling	Air Cooled	Similar. Both methods of cooling are sufficient for the specific design.
Maximum Coil Temperature	43°C	44°C	Similar. Both systems will automatically disable if this maximum temperature is reached
TECHNOLOGICAL CHARACTERISTICS			
Device components	1. Mobile console 2. System software with GUI 3. Treatment chair 4. Head support system 5. Coil positioning system	1. Mobile console 2. System software with GUI 3. Treatment chair 4. Head support system 5. Coil positioning system 6. Same Coil for both MT and treatment	Similar

	6. Same coil for both MT and treatment or MT coil and treatment coil 7. Coil Fixture 8. Data Management System	7. Coil fixture 8. Data management system	
Power Source	Power Supply Mobile console: 110Vac, 20A	Power Supply Mobile console: 110Vac, 20A	Same
Frequency range (Hz) at 100%	0.1-30 (MagPro R30) and 0.1-100 (MagPro X100)	1-30	Substantially equivalent with no new or different questions of safety or effectiveness than the predicate device.
Preset range of % MT	0-140%	25-140%	
Pulse train duration range (sec)	1-33	1-20	
Inter-train interval range (sec)	0.1-120 (±2%)	10-60	
Available Stimulation Intensity in terms of Standard Motor Threshold (SMT) units	Ranging from 0 – 2.2 SMT depending on coil capabilities	Range: 0.22 - 2.08 SMT	
Peak magnetic field strength (T) at a depth of 2cm	Ranging from 0.46 – 0.55T depending on coil capabilities.	0.5T	Substantially equivalent with no new or different questions of safety or effectiveness than the predicate device.
Peak magnetic field gradient dB/dt (kT/s) at a depth of 2cm	Ranging from 9 – 12 kT/s depending on coil capabilities	11 kT/s	
PERFORMANCE DATA			
Electrical Safety & Electromagnetic Compatibility	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	

VII. 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
No clinical performance data were included in this submission.

VIII. PERFORMANCE TESTING SUMMARY

The MagVenture TMS Therapy System is substantially equivalent to the NeuroStar Advanced Therapy System (K230029) in terms of intended use, indications for use, treatment parameters, principles of operation, and overall technological characteristics. Differences between the devices—such as coil design, cooling method, and pulse width—do not raise new or different questions of safety and effectiveness. The Beam F3 Marking Plate provides an alternative, validated method for coil positioning, which is functionally equivalent to the standard 5.5 cm method used in TMS treatments.

Conclusion: The MagVenture TMS Therapy System, with the proposed modifications, maintains substantially equivalent safety, effectiveness, and intended use as the predicate device. The modifications do not introduce new or different questions of safety or effectiveness.
Therefore, the device is substantially equivalent to the NeuroStar Advanced Therapy System (K230029).