April 17, 2025

Brain Ultimate, Inc.
℅ Barry Ashar
President
Makromed, Inc.
88 Stiles Road
Salem, New Hampshire 03079

Re: K243459
Trade/Device Name: Ultimate rTMS for OCD (M-series)
Regulation Number: 21 CFR 882.5802
Regulation Name: Transcranial Magnetic Stimulation System For Neurological And Psychiatric Disorders And Conditions
Regulatory Class: Class II
Product Code: QCI
Dated: March 26, 2025
Received: March 26, 2025

Dear Barry Ashar:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

Submission Number *(if known)*

K243459

Device Name

Ultimate rTMS for OCD (M-series)

Indications for Use *(Describe)*

The Ultimate rTMS for OCD 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) #:	510(k) Summary	Prepared on: 2024-11-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Brain Ultimate, Inc.
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Ultimate rTMS for OCD (M-series)
Common Name	Transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions
Classification Name	Transcranial Magnetic Stimulation System For Obsessive-Compulsive Disorder
Regulation Number	882.5802
Product Code(s)	QCI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K193006	MagVenture TMS Therapy system	QCI

Device Description Summary

21 CFR 807.92(a)(4)

The Ultimate rTMS for OCD is a repetitive transcranial magnetic stimulation (rTMS) system. This computerized medical device produces non-invasive, repetitive pulsed magnetic fields of sufficient magnitude to induce neural action potentials in the prefrontal cortex for the treatment of Obsessive-Compulsive Disorder (OCD).

It can be used in patient care institutions, diagnostics centers, neurosurgical hospitals and experimental laboratories of research institutions.

The Ultimate rTMS principle of operation is based on the discharge of high voltage capacitor through stimulation coil; the pulsed magnetic field generated by the discharge current penetrates through neuromuscular tissues nearby to induce electrical currents in cortical neurons.

Area of the brain to be simulated for ODC treatment is the Dorsomedial Prefrontal Cortex.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device of this 510(k) submission has the exact same Indication for Use as that of the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

Introduction
The proposed device, the Ultimate rTMS for OCD, and the predicate device, the MagVenture TMS Therapy system (K193006) are a computerized electromechanical medical device that produces and delivers non-invasive, repetitive pulsed magnetic fields of sufficient magnitude to induce neural action potentials in the prefrontal cortex for the treatment of Obsessive-Compulsive Disorder (OCD). Both devices have identical intended use/indication for use, identical treatment target, and use identical treatment parameters of the 18-minutes protocol.

Design
The design of the proposed Ultimate rTMS for OCD device is similar to that of the predicate MagVenture TMS Therapy system device, as both systems are based on applying transcranial magnetic stimulation by means of repetitive pulse trains at a predetermined frequency. Both systems use the same mechanism of action, i.e., an electromechanical instrument that produces and delivers brief duration, rapidly alternating (pulsed) magnetic fields to induce electrical currents in localized regions of the prefrontal cortex.
The coil for the proposed Ultimate rTMS for OCD and the predicate device are similar and share the same transducer design (Double-cone).

Operational Characteristics
For the proposed Ultimate rTMS for OCD and its predicate device, their basic operational procedures including system setup, patient preparations, motor threshold determination, coil positioning, and treatment with predefined treatment stimulation parameters are the same. OCD treatment parameters for both devices are the following:
- Magnetic Field Intensity: 100% of the MT
- Frequency: 20 Hz
- Train duration: 2 sec
- Inter-train interval: 20 sec
- Number of trains: 50
- Magnetic Pulses per Session:2000
- Treatment Session Duration: 18.0 min
- Sessions/week: 5
- Treatment Schedule:5 daily sessions for 5 weeks, 4 daily sessions for 1 week
- Area of brain to be stimulated: Dorsomedial Prefrontal Cortex

Technological Characteristics
Both the subject and predicate devices have similar components consisting of TMS stimulator with software, electromagnetic coil and a flexible arm for positioning of the treatment coil.
The predicate MagVenture TMS Therapy system (coil Cool D-B80) and proposed Ultimate rTMS for OCD devices (Coil MY90A) use very similar coils that share the same coil materials, cooling mechanism and media, isolation design, and functionalities.
The reliability of the positioning method used by the proposed Ultimate rTMS for OCD is based on the direct relationship of the underlying cortical brain anatomy to the patient's scalp, as is the method used in the predicate device. The method for identifying the correct treatment position in the proposed device is as effective as the method employed by the predicate device.

The basic operational procedures including system setup, patient preparations, motor threshold determination, coil positioning, and treatment with predefined treatment stimulation parameters are essentially the same between the Ultimate rTMS for OCD device and the predicate device.

Non-clinical Performance Characteristics
1. Electrical/mechanical/thermal safety and electromagnetic compatibility of both the subject and predicate devices have been verified through testing to the following standards:
• IEC 60601-1:2005/(R)2012
• IEC 60601-1-2:2014
2. Patient caps are the only accessory of this device that comes in contact with the patient's intact skin for a duration of less than 24 hours. As they are made of commonly used textile materials they are exempt from ISO 10993-1:2018 Biocompatibility testing per FDA's Guidance Document 'Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"', dated September 8, 2023.
3. The new coil MY90A shares the same double-cone design of the predicate device coil Cool D-B80 (K193006), containing two coils that do not overlap, and allowing for a deeper and broader stimulation of the cortex. To establish substantial equivalence, we have performed a comparison of the magnetic field characteristics of the two coils with their respective systems, in accordance with section 4 of the FDA's Class II Special Controls Guidance Document – Repetitive Transcranial Magnetic Stimulation (rTMS) Systems. These include linearity of output levels, magnetic field strength gradients, output waveform, and magnetic field spatial distribution.

Conclusion
The subject device is equivalent in its performance and does not introduce any new safety considerations in comparison to the predicate device. There are no identified differences between the subject device and the predicate that impact on safety or efficacy.

Criteria	Proposed Device Ultimate rTMS for OCD	Predicate Device MagVenture TMS Therapy system (K193006)	Equivalence Comments
Intended Use (Indication for Use)	The Ultimate rTMS for OCD is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).	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).	Identical
Recommended Standard Treatment			
Magnetic Field Intensity	100% of the MT	100% of the MT	Identical
Frequency	20 Hz	20 Hz	Identical
Train duration	2 sec	2 sec	
Inter-train interval	20 sec	20 sec	
Number of trains	50	50	
Magnetic Pulses per Session	2000	2000	
Treatment Session Duration	18.0 min	18.0 min	
Sessions/week	5	5	Identical
Treatment Schedule	5 daily sessions for 5 weeks, 4 daily sessions for 1 week	5 daily sessions for 5 weeks, 4 daily sessions for 1 week	Identical
Area of brain to be stimulated	Dorsomedial Prefrontal Cortex	Dorsomedial Prefrontal Cortex	Identical
Coils			

Criteria	Proposed Device Ultimate rTMS for OCD	Predicate Device MagVenture TMS Therapy system (K193006)	Equivalence Comments
Coils	MY90A	Cool D-B80	N/A
Configuration	Double-cone coil	Double-cone coil	Identical
Materials of Construction	Coil windings: copper tubing (commercial brand GIS-C1100) Coil housing: polycarbonate (commercial brand Covestro Makrolon PC 2805)	Coil windings: copper tubing (commercial brand unknown) Coil housing: polycarbonate (commercial brand unknown)	Equivalent, with no additional concerns for safety and effectiveness.
Core material	Air core	Air core	Identical
Cooling	Liquid cooling	Liquid cooling	Identical
Coil for MT determination	Used for both MT determination and treatment.	Used for both MT determination and treatment.	Identical
Number of Turns/Wing	8 Upper layer N = 4 turns/wing Lower layer N = 4 turns/wing	7 Upper layer N = 4 turns/wing Lower layer N = 3 turns/wing	Equivalent, with no additional concerns for safety and effectiveness. See Note A for equivalence explanation of coil parameters such as dimensions and windings.
Number of Wings	2	2	
Number of Layers	2	2	

Criteria	Proposed Device Ultimate rTMS for OCD	Predicate Device MagVenture TMS Therapy system (K193006)	Equivalence Comments
Inner Diameter of Winding, mm	50	67	
Outer Diameter of Winding, mm	105	95	
Machine Output Parameters			
Amplitude in Standard Motor Threshold (SMT) units	0 – 2.22 SMT 45% Intensity Setting → 1 SMT	0 – 2.38 SMT 42% Intensity Setting → 1 SMT	Equivalent, with no additional concerns for safety and effectiveness. See Note B for equivalence explanation of Intensity/Amplitude.
Waveform	Biphasic sinusoid	Biphasic sinusoid	Identical
Active pulse width (μs)	300 ±5% （285~315） Measured: 308.6	290 ±5% （275.5~304.5） Measured: 302.2	Equivalent, with no additional concerns for safety and effectiveness. See Note C for equivalence explanation of Pulse Width and Amplitude.
Pulse amplitude (V)	1.240	1.612	
Max magnetic field strength 3 cm from coil (T)	At 25% Intensity: 0.147 At 50% Intensity: 0.225	At 25% Intensity: 0.119 At 50% Intensity: 0.212	Equivalent, with no additional concerns for safety and effectiveness.

Criteria	Proposed Device Ultimate rTMS for OCD	Predicate Device MagVenture TMS Therapy system (K193006)	Equivalence Comments
	At 75% Intensity: 0.297 At 100% Intensity: 0.380	At 75% Intensity: 0.301 At 100% Intensity: 0.391	See Note D for equivalence explanation of Max magnetic field strength.
Max initial dB/dt (kT/s) near the coil surface (z = 0 cm)	21.4	21.9	Equivalent, with no additional concerns for safety and effectiveness. See Note E for equivalence explanation of dB/dt.
Max initial dB/dt (kT/s) 3 cm from coil surface (z = 3 cm)	7.73	8.12	
The system will automatically be disabled when the coil temperature exceeds:	40 °C (104 °F)	41 °C (106 °F)	Regardless of the intensity setting (at Maximum output or otherwise), both the subject and predicate device have a coil temperature safety feature that shuts down the system when the threshold temperature is reached. Ultimate rTMS for OCD system provides a slightly enhanced safety by not letting the coil

Criteria	Proposed Device Ultimate rTMS for OCD	Predicate Device MagVenture TMS Therapy system (K193006)	Equivalence Comments
			temperature exceed 40 ºC compared to 41 ºC for MagVita TMS system.
Frequency range (Hz)	0.1 - 100	0.1 - 30 or 0.1 - 100, depending on model	The differences in these parameters are simply the differences in the overall capabilities of these machines. These capabilities encompass the recommended treatment parameters for OCD listed above. In other words, these variations among different manufacturers' models do not impact their ability to deliver the treatment parameters recommended for OCD. All machines use identical treatment parameters.
Pulse train duration range (s)	Rep Rate: 0.1 ...100Hz Pulses in Train: 1,2,3,4 ... 2000 Train duration = Pulses in Train / Rep Rate	Rep Rate: 0.1 ...100Hz Pulses in Train: 1,2,3,4 ... 1000 Train duration = Pulses in Train / Rep Rate	
Inter-train interval range (s)	0~60s	0~120s	
Maximum trains per session	250	500	
Maximum number of pulses per session	500,000 = 2000 x 250 (Pulses In Train:2000 Maximun Trains:250	500,000 = 1000 x 500 (Pulses in Train:1000 Maximum Trains: 500	
Standards			
Electrical safety	Complies with IEC 60601-1，IEC 60601-1-2.	Complies with IEC 60601-1，IEC 60601-1-2.	N/A
ISO Standards met	Company complies with ISO 13485:2016. ISO14971	Company complies with ISO 13485:2016.	N/A

Note A:

- Applicator Diameter: ID/OD = 50 mm/105 mm for the subject and 67 mm/95 mm for the predicate device. These differences are typical of variations among different manufacturers of TMS devices or even among different models of the same manufacturer. As shown in Section Bench Testing – Section 18 Appendix 18-1 Coils Test Report, they do not lead to significant differences in the electric and magnetic fields generated by these applicators.
- Applicator Windings: Both the subject and the predicate device have the same double-cone design (windings of 2 wings x 2 layers).

Note B:

- Subject Device (Brain Ultimate TMS):
  Intensity/Amplitude Setting = 0% → 0 SMT
  Intensity/Amplitude Setting = 45% → 1 SMT
  Intensity/Amplitude Setting = 100% → 2.22 SMT
- Predicate Device (MagVenture TMS):
  Intensity/Amplitude Setting = 0% → 0 SMT
  Intensity/Amplitude Setting = 42% → 1 SMT
  Intensity/Amplitude Setting = 100% → 2.38 SMT

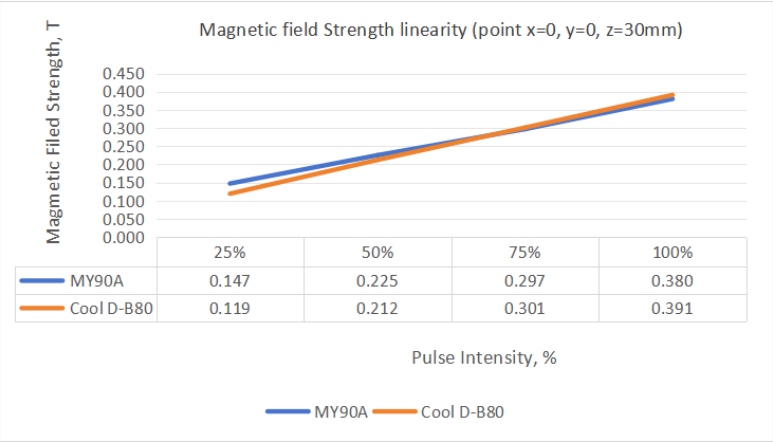
- These are comparable values and within the variations seen among previously cleared TMS devices by the FDA. These differences are typical of variations among different manufacturers of TMS devices or even among different models of the same manufacturer.

Note C:

- Inherent differences in the design and construction of TMS devices of different manufacturers, or even different models of the same manufacturer, lead to the variations in pulse widths shown above. However, since a patient is always treated at 100% MT for OCD on any TMS device, and MT is a function of both the intensity/amplitude and pulse width, differences in pulse widths are easily compensated by the changes in intensity settings needed to achieve 100% MT stimulation.

Note D:

- The Max magnetic field values for the subject and predicate device at 3 cm are in a narrow range and exhibit equivalent slope and intercept values when measured at 25%, 50%, 75% and 100% intensity settings, as shown here:



(See more details in Bench Testing).

- These measurements were made using the same intensity setting on both devices. For a treatment given to the same patient, each device will be set to 100% of the patient's MT, which does not translate to the exact same % power setting on each device. Different power setting on each device for the same MT will compensate for the observed differences in magnetic field strength values in the table.
- These differences are typical of variations among different manufacturers of TMS devices or even among different models of the same manufacturer.

Note E:

- The dB/dt values for the subject and predicate device, at both z = 0 cm and z = 3 cm, are sufficiently close to each other to be considered equivalent. They were measured using the same intensity setting on both devices. For a treatment given to the same patient, each device will be set to 100% of the patient's MT, which does not translate to the exact same % power setting on each device. Different power setting on each device for the same MT will compensate for the observed differences in dB/dt values in the table.
- These differences are typical of variations among different manufacturers of TMS devices or even among different models of the same manufacturer.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following special control document does not specifically list in its scope the subject device of this submission (Product Code QCI, Regulation 882.5802). However, it is applicable to a very similar device (Product Code OBP, Regulation 882.5805) and has specific requirements for what to include in this 510(k) submission:
"Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems."

The following performance tests specified in this guidance document were performed and the results were compared for a determination of substantial equivalence between the subject device (Ultimate rTMS for OCD System) and the predicate device (MagVita TMS System):
Electric Field:
a. SMT Comparison
b. Electrical Field Strength Decay over z-axis distance from coil center (in the direction of head center)

Magnetic Field:
a. Output Waveform for pulse width and amplitude
b. Magnetic Field Strength Linearity as a function of machine intensity setting
c. Magnetic Field Spatial Distribution
d. Magnetic Field Gradient (dB/dt)

Not Applicable

CONCLUSION STATEMENT
The Ultimate rTMS for OCD and the predicate device have identical intended use/indication for use, target population, treatment procedure, treatment position and all recommended standard treatment protocol parameters (intensity, frequency, number of pulses in a train, number of trains in a session, number of treatment sessions).

Both the subject device and the primary predicate device share the same Double Cone coil design. The tested magnetic properties of the Ultimate rTMS for OCD and the primary predicate device are substantial equivalent for the coils.

The reliability of the positioning method used by the Ultimate rTMS for OCD is based on the direct relationship of the underlying cortical brain anatomy to the patient's scalp, as is the method used in the predicate device. The method for identifying the correct treatment position in the Ultimate rTMS for OCD is at least as effective as the method employed by the predicate device.

The Ultimate rTMS for OCD does not introduce any new safety considerations in comparison to the predicate device. All other identified differences between the subject device and the predicate device are minor and without any known impact on safety or efficacy.

Based on the information and supporting documentation provided in the premarket notification, the Ultimate rTMS for OCD is substantially equivalent to the cited primary predicate device. Testing demonstrates that the Ultimate rTMS for OCD fulfills prospectively defined design and performance specifications.