April 17, 2025

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

Re: K243460
Trade/Device Name: Ultimate rTMS
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulation system
Regulatory Class: Class II
Product Code: OBP
Dated: March 20, 2025
Received: March 20, 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)*

K243460

Device Name

Ultimate rTMS

Indications for Use *(Describe)*

The Ultimate rTMS is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medications in the current episode.

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: 2024-11-06

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Brain Ultimate, Inc.
Applicant Address	5910 Shiloh Road East Alpharetta GA 30005 United States
Applicant Contact Telephone	(770) 378-6785
Applicant Contact	Mr. Frank Ge
Applicant Contact Email	Frank.Ge@brainultimate.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Ultimate rTMS
Common Name	Repetitive transcranial magnetic stimulation system
Classification Name	Transcranial Magnetic Stimulator
Regulation Number	882.5805
Product Code(s)	OBP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K173620	Mag Vita TMS Therapy System w/Theta Burst Stimulation	OBP
K171481	Mag Vita TMS Therapy System	OBP

Device Description Summary

21 CFR 807.92(a)(4)

The Ultimate rTMS 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 Major Depressive Disorder.

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 MDD treatment is Left Dorsolateral Prefrontal Cortex.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Ultimate rTMS is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medications in the current episode.

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 subject device, the Ultimate rTMS, and the predicate device, Mag Vita TMS Therapy System, (K173620) are computerized electromechanical medical devices that produce and deliver non-invasive, repetitive pulsed magnetic fields of sufficient magnitude to induce neural action potentials in the prefrontal cortex for the treatment of Major Depressive Disorder. Both devices have identical intended use / indication for use, identical treatment target and use identical treatment parameters of 19-minutes, 37-minutes and iTBS protocols.

Design
The design of the subject Ultimate rTMS device is similar to that of the predicate Mag Vita TMS Therapy System, 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. Coils for subject Ultimate rTMS and the predicate device are of similar nature and share the same transducer design (figure-of-eight).

Operational Characteristics
For the subject Ultimate rTMS 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.

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 reliability of the positioning method used by the subject device 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 devices. The method for identifying the correct treatment position in the subject device is at least as effective as the method employed by the predicate device.

Non-clinical Performance Characteristics
1. Electrical/mechanical/thermal safety and electromagnetic compatibility of both the subject and predicate devices are in compliance with 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 characteristics of the electric and magnetic fields generated by the subject device's coils (BY90A, BF90A, and BY90B), including linearity of output, biphasic sinusoidal waveform, pulse width and intensity, magnetic field spatial distribution and magnetic field strength gradient, are equivalent to that of the predicate device.
4. The subject device meets the same requirement as the predicate device that the actual individual stimuli of a theta burst are of equal intensity to ensure that a constant dose of stimuli is delivered during iTBS treatment (maximum 1% drop in machine output among the three stimuli in a burst).

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	(Subject Device) Ultimate rTMS	(Primary Predicate) MagVita TMS Therapy System (K173620)	(Secondary Predicate) MagVita TMS Therapy System (K171481)	Equivalence Comments
Intended Use (Indication for Use)	The Ultimate rTMS 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.	The 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.	The 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.	Identical Indication for Use
Recommended Standard Treatments				
Magnetic Field Intensity	120% of the MT (iTBS, 19/37 mins protocols)	120% of the MT (iTBS protocol)	120% of the MT (19/37 mins protocol)	Identical recommended treatment parameters. The subject device provides iTBS, 19-min and 37-min protocols. The primary predicate device provides iTBS protocol. The secondary predicate device
Repetition Rate	50 Hz / 10 Hz (iTBS, 19/37 mins protocols)	50 Hz (iTBS protocol)	10 Hz (19/37 mins protocols)	
Train duration	2 sec / 4 sec (iTBS, 19/37 mins protocols)	2 sec (iTBS protocol)	4 sec (19/37 mins protocols)	
Inter-train interval	8 sec / 11-26 sec (iTBS, 19/37 mins protocols)	8 sec (iTBS protocol)	11-26 sec (19/37 mins protocols)	
iTBS Burst	Burst Pulses: 3 No. of Bursts: 200 Inter-pulse: 20 msec	Burst Pulses: 3 No. of Bursts: 200 Inter-pulse: 20 msec	N/A	
Number of trains	20 / 75 (iTBS, 19/37 mins protocols)	20 (iTBS protocol)	75 (19/37 mins protocols)	

Criteria	(Subject Device) Ultimate rTMS	(Primary Predicate) MagVita TMS Therapy System (K173620)	(Secondary Predicate) MagVita TMS Therapy System (K171481)	Equivalence Comments
Magnetic Pulses per Session	600 / 3000 (iTBS, 19/37 mins protocols)	600 (iTBS protocol)	3000 (19/37 mins protocols)	provides 19-min and 37-min protocols.
Treatment Session Duration	3 min 09 sec / 19/37 min (iTBS, 19/37 mins protocols)	3 min 09 sec (iTBS protocol)	19/37 min (19/37 mins protocols)	
Treatment Schedule	5 Sessions/Week for 6 Weeks	5 Sessions/Week for 6 Weeks	5 Sessions/Week for 6 Weeks	
Area of brain to be stimulated	Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex	
Coils				
Coils	BY90A BF90A BY90B	Cool-B70	C-B60 C-B65	N/A
Configuration	BY90A： Figure-of-eight coil BF90A： Figure-of-eight coil BY90B： Figure-of-eight coil-With angle 120°	Figure-of-eight coil	Figure-of-eight coil	Same figure-of-eight configuration in all coils. See Note A.
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)	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	Air core	Same core material design.

Criteria	(Subject Device) Ultimate rTMS	(Primary Predicate) MagVita TMS Therapy System (K173620)	(Secondary Predicate) MagVita TMS Therapy System (K171481)	Equivalence Comments
Cooling	BY90A:Liquid cooling BF90A:Forced Air cooling BY90B:Liquid cooling	Cool-B70: Liquid cooling	C-B60: None C-B65: Liquid cooling	Equivalent. The subject and secondary predicate devices offer liquid-cooled and forced air-cooled or uncooled coils. Primary predicate device offers liquid-cooled coil.
Coil parameters	BY90A Inner diameter - 34 mm Outer diameter - 85 mm N = 2 wings x 2 layers x 5 turns BF90A Inner diameter - 34 mm Outer diameter - 85 mm N = 2 wings x 2 layers x 5 turns BY90B Inner diameter - 30 mm Outer diameter -90 mm N = 2 wings x 2 layers x 6 turns	Coil Cool-B70 Inner diameter - 35 mm Outer diameter - 75 mm N = 2 wings x 2 layers x 5 turns	Coil C-B60 Inner diameter - 35 mm Outer diameter - 75 mm Winding height - 12 mm N = 2 wings x 2 layers x 5 turns Coil Cool-B65 Inner diameter - 35 mm Outer diameter - 75 mm Winding height - 12 mm N = 2 wings x 2 layers x 5 turns	Equivalent, with no additional concerns for safety and effectiveness. See Note A for equivalence explanation of coil parameters such as dimensions and windings.

Criteria	(Subject Device) Ultimate rTMS	(Primary Predicate) MagVita TMS Therapy System (K173620)	(Secondary Predicate) MagVita TMS Therapy System (K171481)	Equivalence Comments
Machine Output Parameters				
Amplitude in Standard Motor Threshold (SMT) units	0 – 2.4 41% Intensity Setting → 1 SMT	0 – 2.1 47% Intensity Setting → 1 SMT	0 - 1.7 58.8% 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	Biphasic sinusoid	Identical waveform.
Active pulse width (μs)	320	290	290	Equivalent, with no additional concerns for safety and effectiveness. See Note C for equivalence explanation of Pulse Width and Amplitude.
Pulse amplitude (V)	BY90A: 1.35 BF90A: 1.26 BY90B: 1.22	C-B70: 1.88	C-B65: 1.84	
Max magnetic field strength 2 cm from coil (T)	<u>At 25% Intensity:</u> BY90A: 0.172 BF90A: 0.182 BY90B: 0.117 <u>At 50% Intensity:</u> BY90A: 0.291	<u>At 25% Intensity:</u> C-B70: 0.144 <u>At 50% Intensity:</u> C-B70: 0.283	<u>At 25% Intensity:</u> C-B65: 0.133 <u>At 50% Intensity:</u> C-B65: 0.272	Equivalent, with no additional concerns for safety and effectiveness.

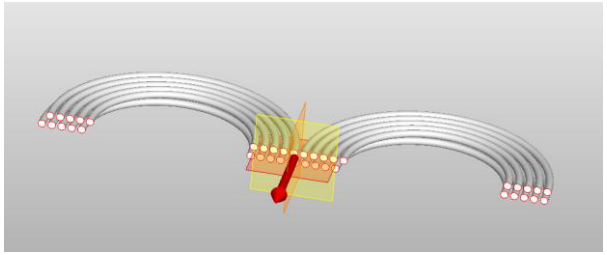
Criteria	(Subject Device) Ultimate rTMS	(Primary Predicate) MagVita TMS Therapy System (K173620)	(Secondary Predicate) MagVita TMS Therapy System (K171481)	Equivalence Comments
	BF90A: 0.287 BY90B: 0.244 <u>At 75% Intensity:</u> BY90A: 0.403 BF90A: 0.395 BY90B: 0.369 <u>At 100% Intensity:</u> BY90A: 0.498 BF90A: 0.494 BY90B: 0.481	<u>At 75% Intensity:</u> C-B70: 0.418 <u>At 100% Intensity:</u> C-B70: 0.549	<u>At 75% Intensity:</u> C-B65: 0.413 <u>At 100% Intensity:</u> C-B65: 0.542	See Note D for equivalence explanation of Max magnetic field strength.
Max initial dB/dt (kT/s) near the coil surface (z = 0 cm)	BY90A: 13.44 BF90A: 13.76 BY90B: 12.10	C-B70: 13.27	C-B65: 13.36	Equivalent, with no additional concerns for safety and effectiveness. See Note E for equivalence explanation of dB/dt.
Max initial dB/dt (kT/s) 2 cm from coil surface (z = 2 cm)	BY90A: 3.59 BF90A: 4.27 BY90B: 6.78	C-B70: 5.25	C-B65: 5.29	
Output Intensity Stability among Pulses in a Burst (Max Change %)	BY90A: 0.563 BF90A: 0.580 BY90B: 0.679	C-B70: 0.615	N/A	Equivalent, with no additional concerns for safety and effectiveness. As established in the predicate device's K173620, it is essential that Output Intensity of

Criteria	(Subject Device) Ultimate rTMS	(Primary Predicate) MagVita TMS Therapy System (K173620)	(Secondary Predicate) MagVita TMS Therapy System (K171481)	Equivalence Comments
				pulses in a burst remain stable with max change of < 1%.
The system will automatically be disabled when the coil temperature exceeds:	40 °C (104 °F)	41 °C (106 °F)	41 °C (104 °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 system provides a slightly enhanced safety by not letting the coil 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	0.1 - 100	The differences in these parameters are simply the differences in the overall capabilities of these machines. These capabilities encompass the recommended
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	Rep Rate: 0.1 ...100Hz Pulses in Train: 1,2,3,4 ... 1000 Train duration = Pulses in Train / Rep Rate	

Criteria	(Subject Device) Ultimate rTMS	(Primary Predicate) MagVita TMS Therapy System (K173620)	(Secondary Predicate) MagVita TMS Therapy System (K171481)	Equivalence Comments
Inter-train interval range (s)	0 - 60	1 - 120	1 - 120	treatment parameters for MDD listed above. In other words, these variations among different manufacturers' models do not impact their ability to deliver the treatment parameters recommended for MDD. All machines use identical treatment parameters.
Maximum trains per session	250	500	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	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.	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 13485:2012.	Company complies with ISO 13485:2012.	N/A

Note A:

- Applicator Diameter: ID/OD = 30-34 mm/85 mm for subject and 35 mm/75 mm for 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 Section18 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 exact same windings of 2 wings x 2 layers x 5 turns in the windings, as illustrated below:



Coil BY90B has 2 x 2 x 6 windings to better accommodate its geometric shape. These differences are typical of variations among different manufacturers of TMS devices or even among different models of the same manufacturer. As a comparison, a TMS device from another manufacturer (Rapid Therapy System, K143531) that is cleared for MDD treatment has a vastly different windings design of 3 x 19 x 2 windings. As shown in Section18 Appendix 18-1 Coils Test Report, they do not lead to significant differences in the electrical and magnetic fields generated by these applicators.

Note B:

- Subject Device (Brain Ultimate TMS):
  Intensity/Amplitude Setting = 0% → 0 SMT
  Intensity/Amplitude Setting = 41% → 1 SMT
  Intensity/Amplitude Setting = 100% → 2.4 SMT

- Predicate Device (MagVita TMS):
  Intensity/Amplitude Setting = 0% → 0 SMT
  Intensity/Amplitude Setting = 47% → 1 SMT
  Intensity/Amplitude Setting = 100% → 2.1 SMT

- These are comparable values and within the variations seen among previously cleared TMS devices by the FDA. These values are in slight favor of Brain Ultimate TMS as they indicate that the subject device will need a slightly lower intensity setting to achieve the same level of induced current as the predicate device.

Note C:

The difference in pulse width (320 +/- 10% vs. 290 +/- 5%) between Brain Ultimate TMS and MagVita TMS is comparable to the differences in pulse widths of several TMS devices cleared by the FDA for MDD treatment, as shown in the table below:

TMS Device	Pulse Width Spec (us)
Brain Ultimate	320 +/- 10% (288-352)
MagVita	290 +/- 5% (275-305)
NeuroStar	185 +/- 10% (166-204)
Magstim	330 +/- 10% (297-363)
Nexstim	235 +/- 5 (230-240)

In the above table:

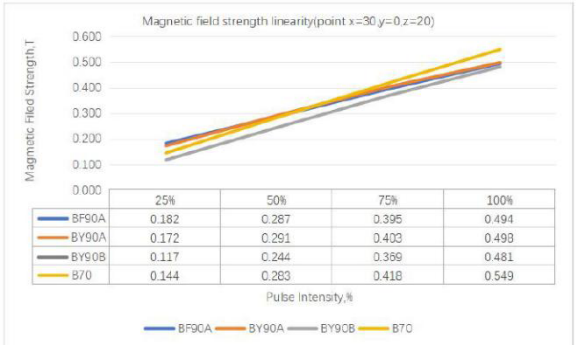
- Subject = Brain Ultimate, Predicate = MagVita

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 120% MT for MDD on any TMS device, and MT is a function of both the intensity/amplitude and pulse width (higher pulse width will require lower intensity/amplitude to reach MT), differences in pulse widths are easily compensated by the changes in intensity settings needed to achieve 120% MT stimulation.

Slightly higher pulse width of Ultimate rTMS compared to MagVita TMS would require slightly lower intensity/amplitude setting on Ultimate rTMS compared to Magvita TMS to achieve the same stimulation level. This is in alignment with Note B above that states that the subject device will need a slightly lower intensity setting to achieve the same level of induced current as the predicate device.

Note D:

- The Max magnetic field values for the subject and predicate device at 2 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:



	25%	50%	75%	100%
BF90A	0.182	0.287	0.395	0.494
BY90A	0.172	0.291	0.403	0.498
BY90B	0.117	0.244	0.359	0.481
B70	0.144	0.283	0.418	0.549

(See more details in Section18 Appendix 18-1 Coils Test Report, pages 7-8).

- 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 120% 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 mm and z = 20 mm, 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 120% 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 is applicable to the subject device (Product Code: OBP) of 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 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)

Also, an additional test (Intensity Variation of Pulses within a Burst) not specified in the guidance document but essential for establishing substantial equivalence for iTBS protocol was performed.

Not Applicable

CONCLUSION STATEMENT
The Ultimate rTMS 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 Figure-of-eight coil design. The tested magnetic properties of the Ultimate rTMS and the primary predicate device are substantial equivalent for the coils. Variation in intensity of individual pulses in a burst are equivalent for the subject and predicate device as both show less than 1% variation.

The reliability of the positioning method used by the Ultimate rTMS 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 is at least as effective as the method employed by the predicate device.

The Ultimate rTMS 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 is substantially equivalent to the cited primary predicate device. Testing demonstrates that the Ultimate rTMS fulfills prospectively defined design and performance specifications.