Wednesday, September 13, 2023

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

Re: K230735
Trade/Device Name: Ultimate rTMS; Yingchi rTMS
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulation system
Regulatory Class: Class II
Product Code: OBP
Dated: August 10, 2023
Received: August 14, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230735

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 medication 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) Summary
for the Brain Ultimate, Inc.
Ultimate rTMS
(*per 21 CFR 807.92 (c)*)

1. SUBMITTER/510(K) HOLDER

Brain Ultimate, Inc.
1185 Park Glenn Drive
Alpharetta, GA 30005, USA

Contact Person:
Barry V. Ashar,
Makromed, Inc.
Telephone: (603) 890-3311
Date Prepared: March 9, 2023

2. DEVICE NAME

Proprietary Name:	Ultimate rTMS (also, Yingchi rTMS)
Regulation Name:	Repetitive transcranial magnetic stimulation system
Regulation Number:	21 CFR §882.5805
Classification Name:	Transcranial Magnetic Stimulator
Device Class:	Class II
Product Code:	OBP

3. PREDICATE DEVICES

- Tonica Electronik A/S, MagVita TMS Therapy System, K171481
- Magstim Company Limited, Rapid^2 Therapy System, K143531

4. DEVICE DESCRIPTION

Transcranial Magnetic Stimulation (TMS) is a painless and non-invasive neuromodulation technique. It directs a magnetic pulse through the intact skull bone to stimulate the underlying brain tissue. The magnetic pulse induces a current flow that activates neurons close to the surface either facilitating or inhibiting their function depending on the protocol.

The Ultimate rTMS is composed of stimulation generator and stimulation coil. The stimulation generator contains a high voltage energy storage capacitor charging and discharging system, an auxiliary power

supply, a microcomputer control system, and a cooling system. The stimulation coil is composed of a stimulation coil, a cooling system, a data collection system, and a communication system.

- Magnetic Stimulator
- Cooling unit
- Coils
    - Coil Figure-of-eight coil (BF90A)
    - Coil Figure-of-eight coil (BY90A)
    - Coil Figure-of-eight coil-With angle 120°(BY90B)
- Trolley (optional)
- Coil holder (optional)
- PC (optional)
- PC keyboard (optional)

5. Intended 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.

6. Standards

The Ultimate rTMS system has been tested and complies with the following standards:

- DIN EN ISO 13485: 2016
- 10993-1:2018
- ISO 14971: 2007
- IEC 60601-1:2005/(R)2012
- IEC 60601-1-2:2014

7. Non-Clinical Performance Data

Electrical safety and electromagnetic compatibility testing demonstrate that the Ultimate rTMS is compliant with IEC 60601-1:2012 and IEC 60601-1-2: 2014.

Only positioning cap in the delivery set of the Ultimate rTMS have direct contact with the patients. The biocompatibility evaluation demonstrates that the positioning cap meet ISO 10993-1:2018 standards.

Software verification and validation testing is described section 16 “Software" following the corresponding FDA software guidelines. It demonstrates that the software performs as intended and in accordance with specifications. The potential risks of the Ultimate rTMS have been identified and

evaluated in compliance with ISO14971:2019, and the risks were determined to be acceptable, or have been addressed with risk control measures.

Additionally, the non-clinical testing with the Ultimate rTMS included testing of the magnetic field characteristics of the system, as required by FDA's guidance document "Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems". The magnetic field plots and acoustic output measurements were conducted to demonstrate safety and performance.

8. Clinical Performance Data

Not applicable. Clinical performance data was not relied upon to demonstrate substantial equivalence.

9. Substantial Equivalence

The Ultimate rTMS and the predicate devices have identical intended use /indication for use and identical treatment parameters and treatment target (see table 5-1). Their technological characteristics are very similar so that they can be considered equivalent.

The design of the Ultimate rTMS is similar to that of the MagVita TMS Therapy System and the Rapid^2 Therapy System, as all systems are based on applying transcranial magnetic stimulation by means of repetitive pulse trains at a predetermined frequency. All 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 basic software capabilities related to treatment administration in the Ultimate rTMS are the same as these in the predicate devices.

To establish substantial equivalence, we have performed comparison of the magnetic field characteristics of the three subject device coils and one predicate device coil 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. Performance testing was conducted to compare the spatial magnetic field distribution of the subject device using all three coils against the predicate device. The same measurement set up was utilized for both systems and that the magnetic field measurements of the four coils (3 subject coils and 1 predicate) were compared on the same plots at multiple locations constituting a holistic quantitative assessment of the output of the two devices.

The Ultimate rTMS and the predicate devices have the same components consisting of TMS stimulator with software, electromagnetic coil and a flexible arm for positioning of the treatment coil. 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. A thorough comparison among the Ultimate rTMS and the predicate devices is shown in a tabular form (see table 5-1) below:

Table 5-1. Side-by-Side Comparison of the Proposed Device with Cited Predicate Devices

Criteria	Ultimate rTMS	(Primary Predicate) MagVita TMS Therapy System (K171481)	(Secondary Predicate) Rapid^2 Therapy System (K143531)	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 Rapid^2 Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.	Identical Indication for Use
Recommended Standard Treatment				
Magnetic Field Intensity	120% of the MT	120% of the MT	120% of the MT	Identical recommended treatment parameters.
Frequency	10 Hz	10 Hz	10 Hz	
Train duration	4 sec	4 sec	4 sec	
Inter-train interval	11-26 sec	11-26 sec	26 sec	The subject and primary predicate devices provide two treatment options – 18.8- and 37.0-minutes treatment durations,
Number of trains	75	75	75	
Magnetic Pulses per Session	3000	3000	3000	

Criteria	Ultimate rTMS	(Primary Predicate) MagVita TMS Therapy System (K171481)	(Secondary Predicate) Rapid^2 Therapy System (K143531)	Equivalence Comments
Treatment Session Duration	18.8-37.0 min	18.8-37.0 min	37.5 min	using 11 sec and 26 sec inter-train intervals.
Sessions/week	5	5	5	
Treatment Schedule	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks	5 daily sessions for 6 weeks	
Area of brain to be stimulated	Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex	Left Dorsolateral Prefrontal Cortex	
Coils				
Coils (including optional accessories)	BY90A BF90A BY90B	C-B60 C-B65	Magstim Double 70mm Air Film Coil	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.
Core material	Air core	Air core	Air core	Same core material design.
Cooling	BY90A:Liquid cooling	C-B65: Liquid cooling	Forced Air	Ultimate rTMS offers liquid-cooled and forced air-cooled coils. Primary predicate offers liquid-cooled coil and secondary predicate offers air-cooled coil.
	BF90A:Forced Air cooling	C-B60: None		
	BY90B:Liquid cooling			

Criteria	Ultimate rTMS	(Primary Predicate) MagVita TMS Therapy System (K171481)	(Secondary Predicate) Rapid^2 Therapy System (K143531)	Equivalence Comments
Coil parameters	BY90A:Inner diameter - 34 mm Outer diameter - 85 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	Area = 33000 mm^2 Average Inductance 12 µH Flat spiral winding N = 2 wings x 3 layers x 19 turns	Equivalent, with no additional concerns for safety and effectiveness. See Note A for equivalence explanation of coil parameters such as dimensions and windings.
	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 C-B60 Inner diameter - 35 mm Outer diameter - 75 mm Winding height - 12 mm N = 2 wings x 2 layers x 5 turns		
Machine Output Parameters				
Amplitude in Standard Motor Threshold (SMT) units	0 - 1.9 52.6% Intensity Setting → 1 SMT	0 - 1.7 58.8% Intensity Setting → 1 SMT	0.28 - 1.9 61.7% 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	300	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-B65: 1.84	N/A	

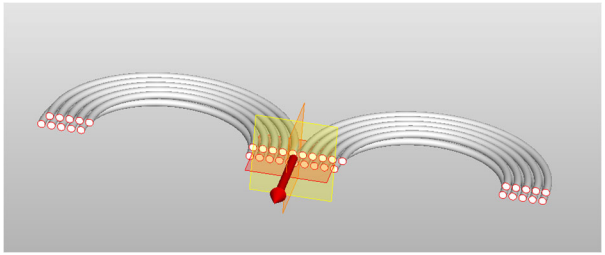
Criteria	Ultimate rTMS	(Primary Predicate) MagVita TMS Therapy System (K171481)	(Secondary Predicate) Rapid^2 Therapy System (K143531)	Equivalence Comments
Max magnetic field strength 2 cm from coil (T)	At 25% Intensity: BY90A: 0.172 BF90A: 0.182 BY90B: 0.117 At 50% Intensity: BY90A: 0.291 BF90A: 0.287 BY90B: 0.244 At 75% Intensity: BY90A: 0.403 BF90A: 0.395 BY90B: 0.369 At 100% Intensity: BY90A: 0.498 BF90A: 0.494 BY90B: 0.481	At 25% Intensity: C-B65: 0.133 At 50% Intensity: C-B65: 0.272 At 75% Intensity: C-B65: 0.413 At 100% Intensity: C-B65: 0.542		Equivalent, with no additional concerns for safety and effectiveness. 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-B65: 13.36	N/A	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-B65: 5.29	N/A	
The system will automatically be disabled when the	40 °C (104 °F)	41 °C (106 °F)	40 °C (104 °F)	Regardless of the intensity setting (at Maximum output or otherwise), both the

Criteria	Ultimate rTMS	(Primary Predicate) MagVita TMS Therapy System (K171481)	(Secondary Predicate) Rapid^2 Therapy System (K143531)	Equivalence Comments
coil temperature exceeds:				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 ^{o}C compared to 41 ^{o}C for MagVita TMS system.
Frequency range (Hz)	0.1 - 10	0.1 - 30 or 0.1 - 100, depending on model	0.1 - 30	The differences in these parameters are simply the differences in the overall capabilities of these machines. These capabilities encompass the recommended 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.
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	1 - 20	
Inter-train interval range (s)	0~60s	1 - 120	10 - 60	
Maximum trains per session	250	500	~140	
Maximum number of pulses per session	5000 (Pluses In Train:20 *Maximun Trains:250 =Maximun Number:5000)	500,000 = 1,000 (pulses max per train) x 500 (trains max per session)	65,000	

Criteria	Ultimate rTMS	(Primary Predicate) MagVita TMS Therapy System (K171481)	(Secondary Predicate) Rapid^2 Therapy System (K143531)	Equivalence Comments
				All machines use identical treatment parameters.
Standards				
Electrical safety	Complies with IEC 60601-1，IEC 60601-1-2.	Complies with IEC 60601-1, IEC 60601-1-1 and IEC 60601-1-2.	Complies with EN 60601-1 and EN 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: 2003 ISO 10993-1: 2009 ISO 14971	N/A

Note A:

- Applicator Diameter: ID/OD = 30-34 mm/85 mm for subject and 35 mm/75 mm for predicate device. The results from our performance testing indicate that the difference in applicator diameter does not result in significant variances in the electrical and magnetic fields. This minor difference will not impact safety or effectiveness.
- Applicator Windings: Even though previously listed as 2 x 10 for the NQ TMS and 2 x (2 x 5) for the MagVita TMS, these are exactly the same windings design of the subject and predicate device, representing 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. The results from our performance testing indicate that the difference in applicator windings does not result in significant variances in the electrical and magnetic fields. This minor difference will not impact safety or effectiveness.

Note B:

- Subject Device (Brain Ultimate TMS):
  Intensity/Amplitude Setting = 0% → 0 SMT
  Intensity/Amplitude Setting = 100% → 1.9 SMT

- Predicate Device (MagVita TMS):
  Intensity/Amplitude Setting = 0% → 0 SMT
  Intensity/Amplitude Setting = 100% → 1.7 SMT

In the FDA rTMS guidance, 1.0 SMT is the output setting of a rTMS device that corresponds to an induced electric field of 130V/m at a point located at the fixed distance of the target along the central axis of the coil from the surface of the scalp into the cortex. This induced electric field is measured with a pick-up loop with the dipole oriented along the front-to-back

- Since the relationship between intensity setting and induced current is linear, the above values translate to the following comparison between the subject and predicate device:
  Subject Device Intensity/Amplitude Setting corresponding to 1 SMT = 52.6% (1/1.9)
  Predicate Device Intensity/Amplitude Setting corresponding to 1 SMT = 58.8% (1/1.7)

- These values indicate the Brain Ultimate TMS will need a slightly lower intensity setting to achieve the same level of induced current as the predicate device. Therefore, this difference is minor and will not impact safety or efficacy.

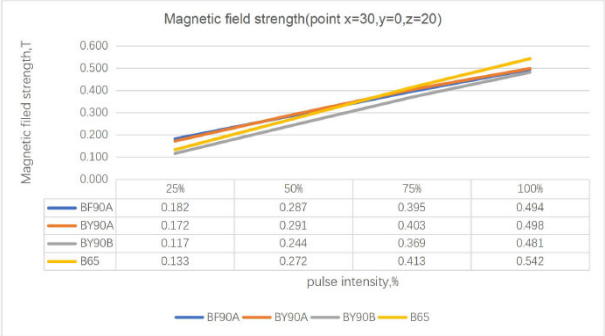
Note C:

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. Therefore, the pulse width is substantially equivalent to the predicate devices and this minor difference will not impact safety or effectiveness.

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:



(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.
- Therefore, our performance testing demonstrates that this difference does not impact safety or effectiveness.

Note E:

- The dB/dt values for the subject and predicate device, at both z = 0 cm and z = 20 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 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.

10. CONCLUSION

The Ultimate rTMS and the predicate devices 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).

All coils compared in Table 5.1 share the same transducer design (figure-of-eight). The tested magnetic properties of the Ultimate rTMS and the predicate devices are substantial equivalent for the coils.

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 devices. The method for identifying the correct treatment position in the Ultimate rTMS is at least as effective as the method employed by the predicate devices.

The Ultimate rTMS does not introduce any new safety considerations in comparison to the predicate device. All other identified differences between the two systems 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 predicate devices. Testing demonstrates that the Ultimate rTMS fulfills prospectively defined design and performance specifications.