September 14, 2025

TeleEMG, LLC
℅ Ashar Barry
President
Makromed, Inc.
88 Stiles Road
Salem, New Hampshire 03079

Re: K250689
Trade/Device Name: CloudTMS Edge
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulation system
Regulatory Class: Class II
Product Code: OBP
Dated: March 5, 2025
Received: March 6, 2025

Dear Ashar Barry:

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

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Pamela D. Scott
Assistant Director
DHT5B: Division of Neuromodulation and
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Physical Medicine Devices
Office of Product Evaluation and Quality
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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.

Form Approved OMB N 0910-012 Expiration Date: 07/31/20 See PI Statemen below.

Submission Number (if known)

K250689

Device Name

CloudTMS Edge

Indications for LJse (Describe)

The CloudTMS Edge system 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K250689

510(k) Summary

Prepared on: 2025-09-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	TeleEMG, LLC
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CloudTMS Edge
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
K173441	CloudTMS	OBP

Device Description Summary

21 CFR 807.92(a)(4)

The CloudTMS Edge 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 [redacted]

The CloudTMS Edge principle of operation is based on the discharge of high voltage capacitor (1.8 kV) through stimulation coil; the pulsed magnetic field generated by the discharge current (up to 10 kA) penetrates through neuromuscular tissues nearby to induce electrical currents in cortical neurons.

Area of the brain to be stimulated for MDD treatment is Left Dorsolateral Prefrontal Cortex.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The CloudTMS Edge system 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 devices.

Technological Comparison

21 CFR 807.92(a)(6)

Introduction
The CloudTMS Edge 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 subject device and the predicate devices (our own CloudTMS and MagVita TMS Therapy System) have identical intended use/indication for use, identical treatment target, and identical treatment parameters of 19-minutes, 37-minutes, and iTBS protocols.

Design
The design of the CloudTMS Edge is similar to that of the our CloudTMS and MagVita TMS 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. Coils for the subject CloudTMS Edge and the predicate devices are of a similar nature and share the same transducer design (figure-of-eight).

Operational Characteristics
For the subject CloudTMS Edge and its predicate devices, 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
The subject and predicate devices have similar components consisting of TMS stimulator with software, electromagnetic coils 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 device. 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
Electrical/mechanical/thermal safety and electromagnetic compatibility of both the subject and predicate devices are in compliance with the standards IEC 60601-1:2005/(R)2012 and IEC 60601-1-2:2014.

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.

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 first stimuli and the third stimuli in a burst during session).

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

Area	(Subject Device) CloudTMS Edge	(Primary Predicate) MagVita TMS Therapy K173620	(Secondary Predicate) CloudTMS K173441	Comments
Indications for use	The **CloudTMS Edge** 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 w/Theta Burst Stimulation** are indicated for Treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.	The **Cloud TMS** 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 Treatment				
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 protocols)	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 provides 19-min and 37-min protocols.
Frequency	50 Hz / 10 Hz (iTBS, 19/37 mins protocols)	50 Hz (iTBS protocol)	10 Hz (19/37 mins protocols)	
Train duration	2 s / 4 s (iTBS, 19/37 mins protocols)	2 s (iTBS protocol)	4 s (19/37 mins protocols)	
Inter-train interval	8 s / 11-26 s (iTBS, 19/37 mins protocols)	8 s (iTBS protocol)	11-26 s (19/37 mins protocols)	
Number of trains	20 / 75 (iTBS, 19/37 mins protocols)	20 (iTBS protocol)	75 (19/37 mins protocols)	
iTBS Burts	Burst Pulses: 3 No. of Bursts: 200 Inter-pulse: 20 msec	Burst Pulses: 3 No. of Bursts: 200 Inter-pulse: 20 msec	N/A	
Magnetic Pulses per Session	600 / 3000 (iTBS, 19/37 mins protocols)	600 (iTBS protocol)	3000 (19/37 mins protocols)	
Treatment Session Duration	3min 12s / 18.8min - 37.0 min (iTBS, 19/37 mins protocols)	3min 12s (iTBS protocol)	18.8min - 37.0 min (19/37 mins protocols)	

Area	(Subject Device) CloudTMS Edge	(Primary Predicate) MagVita TMS Therapy K173620	(Secondary Predicate) CloudTMS K173441	Comments
Sessions/wk	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				
Configuration	**FEC-02-100-C:** Figure-of-eight coil **AFEC-02-100-C:** Figure-of-eight coil **FEC-03-100-C:** Figure-of-eight coil **AFEC-03-100-C:** Figure-of-eight coil **FEC-04-100-AC:** Figure-of-eight coil	**Cool B70:** Figure-of-eight coil	**FEC-02-100-C:** Figure-of-eight coil **AFEC-02-100-C:** Figure-of-eight coil **FEC-02-100 (Optional):** Figure-of-eight coil **AFEC-02-100 (Optional):** 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	**FEC-02-100-C:** Liquid cooling **AFEC-02-100-C:** Liquid cooling **FEC-03-100-C:** Liquid cooling **AFEC-03-100-C:** Liquid cooling **FEC-04-100-AC:** Forced Air cooling	**Cool B70:** Liquid cooling	**FEC-02-100-C:** Liquid cooling **AFEC-02-100-C:** Liquid cooling **FEC-02-100 (Optional):** Air **AFEC-02-100 (Optional):** Air	Equivalent. The subject and secondary predicate devices offer liquid-cooled and forced air-cooled or uncooled coils. The primary predicate

Area	(Subject Device) CloudTMS Edge	(Primary Predicate) MagVita TMS Therapy K173620	(Secondary Predicate) CloudTMS K173441	Comments
				device offers a liquid-cooled coil.
Coil parameters	**FEC-02-100-C:** ID - 50 mm OD - 100 mm N= 2 wings x 2 layers x 4 turns **AFEC-02-100-C:** ID – 51 mm OD – 106 mm N= 2 wings x 2 layers x 4 turns **FEC-03-100-C:** ID - 50 mm OD - 105 mm N= 2 wings x 2 layers x 4 turns **AFEC-03-100-C:** ID - 52 mm OD - 105 mm N= 2 wings x 2 layers x 4 turns **FEC-04-100-AC:** ID - 55 mm OD - 100 mm N= 2 wings x 2 layers x 4 turns	**Cool B70:** ID - 23 mm OD - 97 mm NW= 2 wings x 11 turns	**FEC-02-100-C:** ID - 50 mm OD - 100 mm N= 2 wings x 2 layers x 4 turns **AFEC-02-100-C:** ID – 51 mm OD – 106 mm N= 2 wings x 2 layers x 4 turns **FEC-02-100 (Optional):** ID - 23 mm OD - 97 mm N= 2 wings x 2 layers x 4 turns **AFEC-02-100 (Optional):** ID - 51 mm OD - 106 mm N= 2 wings x 2 layers x 4 turns	Equivalent, with no additional concerns for safety and effectiveness. See **Note A** for equivalence explanation of coil parameters such as dimensions and windings.
Machine Output Parameters				

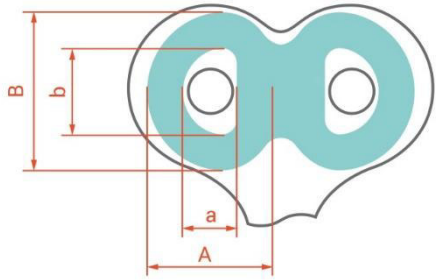
Area	(Subject Device) CloudTMS Edge	(Primary Predicate) MagVita TMS Therapy K173620	(Secondary Predicate) CloudTMS K173441	Comments
Amplitude in Standard Motor Threshold (SMT) units	**FEC-02-100-C:** 0 – 2.0 50% Intensity Setting -> 1 SMT **AFEC-02-100-C:** 0 – 2.3 43% Intensity Setting -> 1 SMT **FEC-03-100-C:** 0 – 2.2 46% Intensity Setting -> 1 SMT **AFEC-03-100-C:** 0 – 3.1 32% Intensity Setting -> 1 SMT **FEC-04-100-AC:** 0 – 1.9 52% Intensity Setting -> 1 SMT	**Cool B70:** 0 – 1.9 52% Intensity Setting -> 1 SMT	**FEC-02-100-C:** 0 – 1.9 53% Intensity Setting -> 1 SMT **AFEC-02-100-C:** 0 – 2.3 44% Intensity Setting -> 1 SMT **FEC-02-100 (Optional):** 0 – 1.9 52% Intensity Setting -> 1 SMT **AFEC-02-100 (Optional):** 0 – 2.3 42% Intensity Setting -> 1 SMT	Equivalent, with no additional concerns for safety and effectiveness. See **Note B** for equivalence explanation of Intensity/Amplitude.
Pulse Width (µs)	**FEC-02-100-C:** 280 **AFEC-02-100-C:** 265 **FEC-03-100-C:** 280 **AFEC-03-100-C:** 290 **FEC-04-100-AC:** 305	**Cool B70:** 310	**FEC-02-100-C:** 260 **AFEC-02-100-C:** 260 **FEC-02-100 (Optional):** 300 **AFEC-02-100 (Optional):** 290	Equivalent, with no additional concerns for safety and effectiveness. See **Note C** for equivalence explanation of Pulse Width and Amplitude.

Area	(Subject Device) CloudTMS Edge	(Primary Predicate) MagVita TMS Therapy K173620	(Secondary Predicate) CloudTMS K173441	Comments
Max initial dB/dt (kT/s) near the coil surface	**FEC-02-100-C:** 25 **AFEC-02-100-C:** 28 **FEC-03-100-C:** 25 **AFEC-03-100-C:** 28 **FEC-04-100-AC:** 20	**Cool B70:** 23	**FEC-02-100-C:** 24 **AFEC-02-100-C:** 28	Equivalent, with no additional concerns for safety and effectiveness.
Max initial dB/dt (kT/s) at 20mm from coil surface	**FEC-02-100-C:** 10 **AFEC-02-100-C:** 11 **FEC-03-100-C:** 10 **AFEC-03-100-C:** 14 **FEC-04-100-AC: 9**	**Cool B70:** 8	**FEC-02-100-C:** 9 **AFEC-02-100-C:** 11	Equivalent, with no additional concerns for safety and effectiveness.
Waveform	Biphasic sinusoid	Biphasic sinusoid	Biphasic sinusoid	Identical waveform.
The system will automatically be disabled when the coil temperature exceeds:	41 ^{o}C (106 ^{o}F)	41 ^{o}C (106 ^{o}F)	41 ^{o}C (106 ^{o}F)	Identical
Frequency range (Hz)	0.1 – 30 (Stand-alone) 0.1 – 100 (with PC)	0.1 - 30 or 0.1 - 100, depending on model	0.1 – 30 (Stand-alone) 0.1 – 100 (with PC)	The differences in these parameters are simply

Area	(Subject Device) CloudTMS Edge	(Primary Predicate) MagVita TMS Therapy K173620	(Secondary Predicate) CloudTMS K173441	Comments
Pulse train duration range (s)	0.5 – 100	Rep Rate: 0.1 ...100Hz Pulses in Train: 1,2,3,4 ... 1000 Train duration = Pulses in Train / Rep Rate	0.5 – 100	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. All machines use identical treatment parameters.
Inter-train interval range (s)	0 – 300	1 - 120	0 – 300	
Maximum trains per session	4800 = 2400s [max session] / (0.5 s [min train] + 0 sec [min pause])	500	4800 = 2400s [max session] / (0.5 s [min train] + 0 sec [min pause])	
Maximum # of pulses per session (cumulative exposure)	72000(Stand-alone) =2400s [max session] *30Hz 240000(with PC) =2400s [max session] *100Hz	500,000 = 1,000 (pulses max per train) x 500 (trains max per session)	72000(Stand-alone) =2400s [max session] *30Hz 240000(with PC) =2400s [max session] *100Hz	
Standards				
Electrical Safety and Electromagnetic Compatibility	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	N/A
ISO Standards	ISO13485:2012 ISO 10993-1:2009 ISO 14971:2007	ISO 13485:2012	ISO13485:2012 ISO 10993-1:2009 ISO 14971:2007	N/A

Note A:

- Applicator Diameter: ID/OD differences are typical of variations among different manufacturers of TMS devices or even among different models of the same manufacturer. As shown in Section 18 Appendix 18-1 Performance Testing - Bench Top Study, 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 devices have the same number of windings (2 wings) and figure-of-eight, as illustrated below:



Layers and turns 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 Section 18 Appendix 18-1 Performance Testing - Bench Top Study, they do not lead to significant differences in the electrical and magnetic fields generated by these applicators.

Note B:

- Subject Device (CloudTMS Edge, Coil **FEC-02-100-C**):
  Intensity/Amplitude Setting = 0% → 0 SMT
  Intensity/Amplitude Setting = 50% → 1 SMT
  Intensity/Amplitude Setting = 100% → 2.0 SMT
- Subject Device (CloudTMS Edge, Coil **AFEC-02-100-C**):
  Intensity/Amplitude Setting = 0% → 0 SMT
  Intensity/Amplitude Setting = 43% → 1 SMT
  Intensity/Amplitude Setting = 100% → 2.3 SMT

- Subject Device (CloudTMS Edge, Coil **FEC-03-100-C**):
  Intensity/Amplitude Setting = 0% → 0 SMT
  Intensity/Amplitude Setting = 46% → 1 SMT
  Intensity/Amplitude Setting = 100% → 2.2 SMT
- Subject Device (CloudTMS Edge, Coil **AFEC-03-100-C**):
  Intensity/Amplitude Setting = 0% → 0 SMT
  Intensity/Amplitude Setting = 32% → 1 SMT
  Intensity/Amplitude Setting = 100% → 3.1 SMT
- Subject Device (CloudTMS Edge, Coil **FEC-04-100-AC**):
  Intensity/Amplitude Setting = 0% → 0 SMT
  Intensity/Amplitude Setting = 52% → 1 SMT
  Intensity/Amplitude Setting = 100% → 1.9 SMT

- Primary Device (MagVita TMS, Coil **Cool B70**):
  Intensity/Amplitude Setting = 0% → 0 SMT
  Intensity/Amplitude Setting = 52% → 1 SMT
  Intensity/Amplitude Setting = 100% → 1.9 SMT

- Reference Device (CloudTMS, Coil **FEC-02-100-C**):
  Intensity/Amplitude Setting = 0% → 0 SMT
  Intensity/Amplitude Setting = 53% → 1 SMT
  Intensity/Amplitude Setting = 100% → 1.9 SMT
- Reference Device (CloudTMS, Coil **AFEC-02-100-C**):
  Intensity/Amplitude Setting = 0% → 0 SMT
  Intensity/Amplitude Setting = 44% → 1 SMT
  Intensity/Amplitude Setting = 100% → 2.3 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 CloudTMS Edge 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 devices (K173620 and K173441).

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. Inherent differences in the design and construction of TMS devices of different manufacturers, or even different models of the same manufacturer, lead to variations in pulse widths.

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

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 (CloudTMS Edge) and the predicate devices (MagVita TMS Therapy System and CloudTMS):
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

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.

[redacted]

CONCLUSION STATEMENT
The CloudTMS Edge 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).

Both the subject device and the predicate devices share the same Figure-of-eight coil design. The tested magnetic properties of the CloudTMS Edge and the predicate devices are substantial equivalent for the coils. Variation in intensity of individual pulses in a burst for the subject device show less than 1% variation.

The reliability of the positioning method used by the CloudTMS Edge 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 CloudTMS Edge is as effective as the method employed by the predicate devices.

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

Based on the information and supporting documentation provided in the premarket notification, the CloudTMS Edge is substantially equivalent to the cited predicate devices. Testing demonstrates that the CloudTMS Edge fulfills prospectively defined design and performance specifications.