



December 22, 2023

TeleEMG, LLC
% Barry Ashar
President
Makromed, Inc.
88 Stiles Road
Salem, NH 03079

Re: K233742

Trade/Device Name: CloudTMS Edge for OCD

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: November 10, 2023

Received: November 22, 2023

Dear Mr. 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.

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 M. Stefani Digitally signed by Robert M.
Stefani -S
-S Date: 2023.12.22 14:50:02 -05'00'

for Pamela Scott, MS
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

Device Name

CloudTMS Edge for OCD

Indications for Use (Describe)

The CloudTMS Edge 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) Summary

Prepared on: 2023-11-20

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	TeleEMG, LLC
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Correspondent Address	88 Stiles Road Salem NH 03079 United States
Correspondent Contact Telephone	6036749074
Correspondent Contact	Mr. Barry Ashar
Correspondent Contact Email	bashar@makromed.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	CloudTMS Edge for OCD
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	QCI

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221129	CloudTMS for OCD	QCI

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The CloudTMS Edge 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.

General functionalities provided by the system are:
- Single pulse stimulation (motor threshold detecting)

- Repetitive stimulation (therapy)
- Patient's data entering
- Stimulation algorithm editing
- Review of stimulation history
- Treatment report generation and printing
- Operation with list of treatment (selection for review, removal, etc.).

The CloudTMS Edge for OCD 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 OCD treatment is Dorsomedial Prefrontal Cortex.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The CloudTMS Edge 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 (CloudTMS Edge for OCD) and the predicate device (Cloud TMS for OCD) are a repetitive transcranial magnetic stimulation (rTMS) systems. These computerized medical devices produce non-invasive, repetitive pulsed magnetic fields of sufficient magnitude to induce neural action potentials in the bilateral dorsomedial prefrontal cortex (DMPFC) for the treatment of Obsessive-Compulsive Disorder (OCD). Both devices have identical intended use / indication for use and identical treatment parameters and treatment target.

Design

The design of the two systems are near identical as both systems are based on applying transcranial magnetic stimulation by means of repetitive pulse trains at a predetermined frequency of 20 Hz. 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 bilateral dorsomedial prefrontal cortex (DMPFC). Both systems use the exact same coil DCC-03-125-C, with a double cone coil transducer design. Both systems use the exact same software.

Operational Characteristics

For both the subject and the predicate device, their basic operational procedures including system setup, patient preparations, motor threshold determination, coil positioning and treatment with predefined treatment stimulation parameters are identical.

Technological Characteristics

The subject device and the predicate device use the exact same components and accessories, with the exception that the predicate device's main unit has been modified/enhanced with the following features in the subject device:

1. Automatic detection and adjustment to the supply main power input of 110V or 220V.
2. Upgraded power supply that provides faster charging of the voltage capacitor.
3. Obsolescence and replacement of previous hydraulic quick couplers used for cooled coil connections.
4. Improved graphical user interface to enhance user experience.

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. Since the subject device uses the exact same patient caps as the predicate device, their biocompatibility characteristics are identical.
3. Since both devices use the exact same double cone coil and the exact same treatment parameters, the characteristics of the electric and magnetic fields generated by them are identical. These include linearity of output, biphasic sinusoidal waveform, pulse width and intensity, magnetic field spatial distribution and magnetic field strength gradient.

Conclusion

The subject device, CloudTMS Edge for OCD, does not introduce any new safety or effectiveness considerations in comparison to the predicate device, CloudTMS for OCD. All identified modifications between the two systems are minor and have been verified to not have any known impact on safety or efficacy.

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

Non-clinical Test Summary and Conclusion

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. Since the subject device uses the exact same patient caps as the predicate device, their biocompatibility characteristics are identical.

3. Since both devices use the exact same double cone coil and the exact same treatment parameters, the characteristics of the electric and magnetic fields generated by them are identical. These include linearity of output, biphasic sinusoidal waveform, pulse width and intensity, magnetic field spatial distribution and magnetic field strength gradient.

Conclusion

The subject device, CloudTMS Edge for OCD, does not introduce any new safety or effectiveness considerations in comparison to the predicate device, CloudTMS for OCD. All identified modifications between the two systems are minor and have been verified to not have any known impact on safety or efficacy.