December 13, 2017

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

Re: K173441
Trade/Device Name: Neurosoft TMS (also CloudTMS)
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: October 23, 2017
Received: November 6, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William J. Heetderks -S
2017.12.13 12:00:03 -05'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173441

Device Name
Neurosoft TMS

Indications for Use *(Describe)*
The Neurosoft TMS 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 TeleEMG, LLC
Neurosoft TMS

(*per 21 CFR 807.92 and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm*)

1. SUBMITTER/510(K) HOLDER

TeleEMG, LLC
27 Arlington Rd., Building 2, Unit 1
Woburn, MA 01801, USA

Contact Person:
Barry V. Ashar,
Makromed, Inc.
Telephone: (603) 890-3311
Date Prepared: October 12, 2017

2. DEVICE NAME

Proprietary Name:	Neurosoft TMS
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

- TeleEMG LLC, Neurosoft TMS, K160309
- Tonica Electronik A/S, MagVita TMS Therapy System, K171481

4. SPECIAL CONTROLS

The 510k submission addressed the special controls required by regulation and specified in the FDA guidance document titled "Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems.

5. DEVICE DESCRIPTION

The Neurosoft TMS 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.

The Neurosoft TMS 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.

The Neurosoft TMS consists of the following main components:

- Main unit of the magnetic stimulator
- Cooling unit
- Extra power supply unit
- Coils
    - Cooled figure-of-eight coil FEC-02-100-C
    - Cooled figure-of-eight coil AFEC-02-100-C
    - Figure-of-eight coil FEC-02-100 (optional)
    - Figure-of-eight coil AFEC-02-100 (optional)
- K8 coil holder
- K3 flexible arm for coil positioning
- Trolley with casters

6. INTENDED USE/INDICATION FOR USE

The Neurosoft 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.

7. STANDARDS

The Neurosoft TMS system has been tested and complies with the following standards:

- DIN EN ISO 13485: 2012
- ISO 10993-1
- ISO 14971
- IEC 60601-1
- IEC 60601-1-2

7. NON-CLINICAL PERFORMANCE DATA

The non-clinical performance testing of Neurosoft TMS has been tested as required, and cleared by the FDA earlier on K160309. These tests demonstrate that the Neurosoft TMS is safe and effective for use in treatment of Major Depressive Disorder.

8. SUBSTANTIAL EQUIVALENCE

The Neurosoft TMS is substantially equivalent to the predicate devices (our own Neurosoft TMS and MagVita TMS Therapy System). The Neurosoft TMS and the predicate devices have identical intended use /indication for use, and technological characteristics. The principles of operation, the output stimulation parameters and the materials are equivalent to the predicates. The modification to the device allows a range of inter-train intervals from 11 to 26 seconds, rather than the fixed 26 second duration, which will allow a reduction in treatment time from 37.5 minutes to a minimum of 18.8 minutes.

The design of the Neurosoft TMS is similar to that of our predecessor Neurosoft TMS and the 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.

The basic software capabilities related to treatment administration in the Neurosoft TMS are the same as these in the predicate devices.

The Neurosoft TMS 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 Neurosoft TMS and the predicate devices is shown in a tabular form below:

Table: Side-by-Side Comparison of the Proposed Device with Cited Predicate Devices

Criteria	Neurosoft TMS	Neurosoft TMS (K160309)	MagVita TMS Therapy System (K171481)
Intended Use	The Neurosoft TMS is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior	The Neurosoft TMS is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior	The MagVita TMS Therapy System is indicated for the treatment of Major Depressive Disorder in adult patients who have

Criteria	Neurosoft TMS	Neurosoft TMS (K160309)	MagVita TMS Therapy System (K171481)
	antidepressant medication in the current episode.	antidepressant medication in the current episode.	failed to receive satisfactory improvement from prior antidepressant medication in the current episode.
Recommended standard treatment			
Magnetic Field Intensity	120% of the MT	120% of the MT	120% of the MT
Frequency	10 Hz	10 Hz	10 Hz
Train duration	4 sec	4 sec	4 sec
Inter-train interval	11-26 sec	26 sec	11-26 sec
Number of trains	75	75	75
Magnetic Pulses per Session	3000	3000	3000
Treatment Session Duration	18.8 min-37.0 min	37.0 min	18.8 min-37.0 min.
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	Frontal Cortex	Frontal Cortex	Frontal Cortex
Coils			
Coils (including optional accessories)	FEC-02-100-C, AFEC-02-100-C FEC-02-100 (optional), AFEC-02-100 (optional)	FEC-02-100-C, AFEC-02-100-C FEC-02-100 (optional), AFEC-02-100 (optional)	C-B60 C-B65
Configuration	Figure-of-eight coil	Figure-of-eight coil	Figure-of-eight coil
Core material	Air core	Air core	Air core
Cooling	FEC-02-100-C & AFEC-02-100-C: Liquid cooling	FEC-02-100-C & AFEC-02-100-C: Liquid cooling	C-B65: Liquid cooling
	FEC-02-100 & AFEC-02-100 (optional accessories): None	FEC-02-100 & AFEC-02-100 (optional accessories): None	C-B60: None
Coil parameters	FEC-02-100-C Inner diameter - 47x50 mm^1 Outer diameter - 97x100 mm^1 Area = 184725 mm^2 Average Inductance 10 µH Flat spiral winding N = 16 turns (2 layers x 2 wings)	FEC-02-100-C Inner diameter - 47x50 mm^1 Outer diameter - 97x100 mm^1 Area = 184725 mm^2 Average Inductance 10 µH Flat spiral winding N = 16 turns (2 layers x 2	Coil Cool-B65 Inner diameter - 35 mm Outer diameter - 75 mm Winding height - 12 mm N = 2x (2 x 5)

Criteria	Neurosoft TMS	Neurosoft TMS (K160309)	MagVita TMS Therapy System (K171481)
		wings)	
	AFEC-02-100-C Inner diameter - 36x51 mm^1 Outer diameter - 84x106 mm^1 Area = 184725 mm^2 Average Inductance 10 µH Flat spiral winding N = 16 turns (2 layers x 2 wings)	AFEC-02-100-C Inner diameter - 36x51 mm^1 Outer diameter - 84x106 mm^1 Area = 184725 mm^2 Average Inductance 10 µH Flat spiral winding N = 16 turns (2 layers x 2 wings)	
	FEC-02-100 Inner diameter - 47x50 mm^1 Outer diameter - 97x100 mm^1 Area = 91560 mm^2 Average Inductance 10 µH Flat spiral winding N = 16 turns (2 layers x 2 wings)	FEC-02-100 Inner diameter - 47x50 mm^1 Outer diameter - 97x100 mm^1 Area = 91560 mm^2 Average Inductance 10 µH Flat spiral winding N = 16 turns (2 layers x 2 wings)	Coil C-B60 Inner diameter - 35 mm Outer diameter - 75 mm Winding height - 12 mm N = 2x (2 x 5)
	AFEC-02-100 Inner diameter - 36x51 mm^1 Outer diameter - 84x106 mm^1 Area = 87200 mm^2 Average Inductance 10 µH Flat spiral winding N = 16 turns (2 layers x 2 wings)	AFEC-02-100 Inner diameter - 36x51 mm^1 Outer diameter - 84x106 mm^1 Area = 87200 mm^2 Average Inductance 10 µH Flat spiral winding N = 16 turns (2 layers x 2 wings)	
Machine Output Parameters			
Amplitude in Standard Motor Threshold (SMT) units	FEC-02-100-C 0 - 1.89 AFEC-02-100-C 0 - 2.38 FEC-02-100 0 - 1.92 AFEC-02-100 0 - 2.33	FEC-02-100-C 0 - 1.89 AFEC-02-100-C 0 - 2.38 FEC-02-100 0 - 1.92 AFEC-02-100 0 - 2.33	0 - 1.7
Waveform	Biphasic sinusoid	Biphasic sinusoid	Biphasic sinusoid
Active pulse width (µs)	280	280	290
Max initial dB/dt (kT/s) near the coil surface	FEC-02-100-C 25 AFEC-02-100-C 38 FEC-02-100 25 AFEC-02-100 32	FEC-02-100-C 25 AFEC-02-100-C 38 FEC-02-100 25 AFEC-02-100 32	C-B65: 36 C-B60: 35
The system will automatically be disabled when the	41 °C (106 °F)	41 °C (106 °F)	41 °C (106 °F)

Criteria	Neurosoft TMS	Neurosoft TMS (K160309)	MagVita TMS Therapy System (K171481)
coil temperature exceeds:			
Frequency range (Hz)	0.1 - 30 (Stand-alone) 0.1 - 100 (with PC)	0.1 - 30 (Stand-alone) 0.1 - 100 (with PC)	0.1 - 30 or 0.1 - 100, depending on model
Pulse train duration range (s)	0.5 - 100	0.5 - 100	Rep Rate: 0.1 ...100Hz Pulses in Train: 1,2,3,4 ... 1000 Train duration = Pulses in Train / Rep Rate
Inter-train interval range (s)	0 - 300	0 - 300	1 - 120
Maximum trains per session	4800 = 2400 s [max session] / (0.5 s [min train]+ 0 s [min pause])	4800 = 2400 s [max session] / (0.5 s [min train]+ 0 s [min pause])	500
Maximum number of pulses per session	72000(Stand-alone)=2400 s [max session] *30 Hz 240000(with PC)=2400 s [max session] *100 Hz	72000(Stand-alone)=2400 s [max session] *30 Hz 240000(with PC)=2400 s [max session] *100 Hz	N/A
Standards			
Electrical safety	Complies with IEC 60601-1 and IEC 60601-1-2	Complies with IEC 60601-1 and IEC 60601-1-2	Complies with IEC 60601-1, IEC 60601-1-1 and IEC 60601-1-2.
ISO Standards met	Company complies with DIN EN ISO 13485: 2012 ISO 10993-1: 2009 ISO 14971: 2007	Company complies with DIN EN ISO 13485: 2012 ISO 10993-1: 2009 ISO 14971: 2007	Company complies with ISO 13485:2012.

[1] *see Fig. 1*

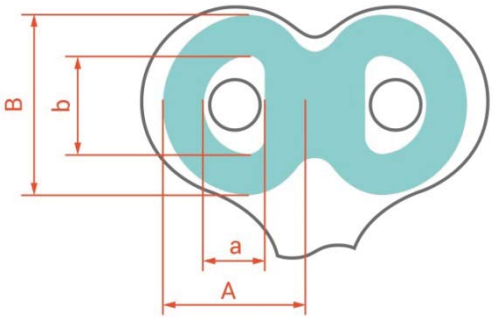

Fig.1 Coil for magnetic stimulator

9. CONCLUSION

The Neurosoft TMS 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 the above Table share the same transducer design (figure-of-eight). The tested magnetic properties of the Neurosoft TMS and the predicate devices are substantial equivalent for the coils.

The reliability of the positioning method used by the Neurosoft TMS 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 Neurosoft TMS is at least as effective as the method employed by the predicate devices.

On the basis of the only modification of the treatment parameter, the Neurosoft TMS 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 Neurosoft TMS is substantially equivalent to the cited predicate devices. Testing demonstrates that the Neurosoft TMS fulfills prospectively defined design and performance specifications.