February 9, 2024

Revital Lab Inc.
Conway Ho
President
2349 Aragon Canyon St
Las Vegas, Nevada 89135

Re: K233631
Trade/Device Name: ZapStim Controller Application (Z1023)
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: November 8, 2023
Received: November 13, 2023

Dear Conway Ho:

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,

Pamela D. Scott -S

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

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)*
K233631

Device Name
ZapStim Controller Application (Z1023)

Indications for Use *(Describe)*
ZapStim Controller Application is intended for use with the Neurosoft TMS system and is indicated for use in delivering the FDA cleared treatment protocol for treatment of Major Depressive Disorder (MDD) in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in their 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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ZapStim Controller Application (K233631) 510(k) Summary

1. CONTACT DETAILS

Applicant Name: Revital Lab Inc.
Applicant Address: 2349 Aragon Canyon St Las Vegas NV 89135 United States
Application Contact Telephone: 5624831414
Applicant Contact: Mr. Conway Ho
Applicant Contact Email: info@revitallabinc.com

2. DEVICE NAME

Device Trade Name: ZapStim Controller Application (Z1023)
Common Name: Repetitive transcranial magnetic stimulation system
Classification Name: Transcranial Magnetic Stimulator
Regulation Number: 882.5805
Product Code: OBP

3. LEGALLY MARKETED PREDICATE DEVICES

Predicate #: K173441
Predicate Trade Name (Primary Predicate is listed first): Neurosoft TMS (also CloudTMS)
Product Code: OBP

4. DEVICE DESCRIPTION SUMMARY

ZapStim Controller Application is a software application that is indicated to be used by clinicians for the treatment of Major Depressive Disorder. The software resides on a computer system and functions by controlling a third party TMS system (Neurosoft Cloud TMS system, K173441). ZapStim Controller Application software is to be used in place of the Neurosoft TMS User interface for setting certain aspects of the treatment administered by the TMS system. The third party TMS system will physically deliver the therapy to the patient. The ZapStim Controller Application is compatible with the Neurosoft TMS System, K173441, and it is intended to be used in tandem with the Neurosoft TMS System to provide treatment.

The software includes a user interface that allows the user to control limited aspects of the treatment administered by the TMS system. The system is currently intended to deliver the FDA cleared treatment protocol for MDD as stated in the indications for use.

The ZapStim software is compatible and is to be used in tandem with the specific Neurosoft TMS System components listed below:

- Main unit of the magnetic stimulator
- Cooling unit
- Extra power supply unit
- Cooled figure-of-eight coil AFEC-02-100-C
- USB A to B cable

See 510(k) submission K173441 for further information on the Neurosoft TMS device.

The ZapStim Controller Application consists of the following main components:

- ZapStim Application (ZapStim.exe)
- Simulator Driver (stimneurosoft.exe)

Both components are utilized when using the device.

The ZapStim Controller Application is to be distributed predownloaded onto a commercial off the shelf PC.

The ZapStim Controller Application is to be accessed on the PC, and the PC is to be connected via USB to the Neurosoft TMS System. The ZapStim Controller Application can be used to select the treatment protocol to be administered, which at this time will only be the FDA cleared treatment protocol for MDD in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in their current episode. The user cannot edit the treatment protocol using the ZapStim Controller Application. The user can also start, pause, and end the administration of treatment using the ZapStim Controller Application.

The ZapStim Controller Application relays the treatment protocol information to the Neurosoft TMS System, which then administers the magnetic stimulation.

5. INTENDED USE/INDICATIONS FOR USE

ZapStim controller application is intended for use with the Neurosoft TMS System and is indicated for use in delivering the FDA cleared treatment protocol for treatment of major depressive disorder (MDD) in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in their current episode.

6. INDICATIONS FOR USE COMPARISON

ZapStim Controller Application and the predicate device have a similar intended use/indication for use statement. The subject device is a SaMD and is a subset of the predicate device. The purpose of the software app for both the predicate and subject device is to control the transcranial magnetic stimulation hardware, select the treatment protocol (frequency, train length, intertrain length) and start/stop the delivery of stimulation. Therefore, the intended use is the same for the subject and predicate devices, except that the subject device does not include the hardware components of the predicate device.

7. TECHNOLOGICAL COMPARISON

The ZapStim Controller Application device is a SaMD and does not include a TMS stimulator. The ZapStim Controller Application is intended to control the predicate device's hardware by selecting the treatment protocol (frequency, train length, intertrain length) and starting/stopping the delivery of stimulation during treatment. The subject and predicate software are of the same technology; however, it is designed and developed by different manufacturers.

The other component of the ZapStim (computer) is an accessory of the subject device, which is used to operate the software and interface with the predicate hardware. The ZapStim Controller Application is intended to be used to select the treatment protocol (frequency, train length, intertrain length) and start/stop the delivery of stimulation.

These technological differences between the ZapStim Controller Application and the predicate do not raise any new issues on effectiveness or safety.

Criteria	ZapStim Controller Application	Neurosoft TMS (K173441)

Intended Use	ZapStim Controller Application is indicated for treatment of Major Depressive Disorder (MDD) in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in their current episode.	The Neurosoft TMS is indicated for the treatment of Major Depressive Disorder (MDD) in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.
FDA-cleared standard treatment		
Magnetic Field Intensity	120% of the MT*	120% of the MT
Frequency	10 Hz	10 Hz
Train duration	4 sec	4 sec
Inter-train interval	26 sec	11-26 sec
Number of trains	75	75
Magnetic Pulses per session	3000	3000
Treatment Session Duration	~37 min	18.8-37.0 min
Sessions/week	5*	5
Treatment Schedule	5 daily sessions for 6 weeks*	5 daily sessions for 6 weeks
Area of brain to be stimulated	Frontal Cortex	Frontal Cortex
*These variables are not directly controlled by the subject device		
Coils		
Coils (including optional accessories)	The subject device utilizes the same hardware as the predicate device	FEC-02-100-C, AFEC-02-100-C FEC-02-100 (optional), AFEC-02-100 (optional)
Configuration		Figure-of-eight-coil
Core material		Air core
Cooling		FEC-02-100-C & AFEC-02-100-C: Liquid cooling
		FEC-02-100 & AFEC-02-100 (optional accessories): 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)
	The subject device utilizes the same hardware as the predicate device	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)
		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	The subject device utilizes the same hardware as the predicate device[1]	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
Waveform	Biphasic sinusoid	Biphasic sinusoid
Active pulse width (µs)	The subject device utilizes the same hardware as the predicate device[1]	280
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
The system will automatically be disabled when the coil temperature exceeds:		41 °C (106 °F)
Frequency range (Hz)	1 – 20 Hz	0.1 - 30 (Stand-alone) 0.1 - 100 (with PC)
Pulse train duration range (s)	0.5 - 100	0.5 - 100
Inter-train interval range (s)	0 - 300	0 - 300
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])
Maximum number of pulses per session	The subject device utilizes the same hardware as the predicate device[1]	72000 (Stand-alone) = 2400 s [max session] *30 Hz 240000 (with PC) = 2400 s [max session] *100 Hz
[1]The ZapStim controller application can control the following parameters: Stimulation frequency, pulse		

train duration, inter-train interval, and trains per session. The software can control the hardware to the same parameters as the predicate device.		
Components		
Components	PC ZapStim Controller Application Software	Neurosoft TMS System Hardware Neuro-MS.NET Software

8. NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS

The verification results (RP-5021-1.0.7746) demonstrate that the ZapStim software interface functions with the Neurosoft Cloud TMS hardware as intended and as required. The tests run during verification show that ZapStim Software can perform the functions of starting, stopping, and pausing a train sequence on the Neurosoft CloudTMS (predicate device) as well as determining the train sequence frequency, train length, and intertrain length; these are all functions that the predicate device is also capable of performing. The verification results show that the ZapStim software can control stimulation frequency, pulse train duration, inter-train interval, and trains per session of the CloudTMS system.

The validation results (RP-5022-1.0.7746) demonstrate ZapStim software's ability to control the functions listed above of the rTMS Stimulator system does not negatively alter the accuracy of the frequency set for treatment. At all frequencies tested, there was no statistically significant difference between the frequency set by the ZapStim Software and the frequency delivered by the CloudTMS machine. Waveforms showing the biphasic nature of the stimulation pulse delivered were also included in the validation tests to demonstrate that using the ZapStim Software does not change the waveform shape of the pulse delivered by the CloudTMS system.

Comparison of the intended use, indications for use, technological characteristics, and performance testing demonstrate the substantial equivalence of the subject device ZapStim SW to the legally marketed predicate device, Neurosoft (K173441).

Substantial equivalence between the predicate device (K173441) and the subject device is shown through the verification and validation testing performed on the NT rTMS Software. The subject device is substantially equivalent to the predicated device, K173441.