March 4, 2022

BTL Industries Inc.
David Chmel
VP of Operations
362 Elm Street
Marlborough, Massachusetts 01752

Re: K212723
Trade/Device Name: BTL-995-rTMS
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulation System
Regulatory Class: Class II
Product Code: OBP
Dated: February 9, 2022
Received: February 9, 2022

Dear David Chmel:

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,

for Pamela Scott, PhD
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)*
K212723

Device Name
BTL-995-rTMS

Indications for Use *(Describe)*
BTL-995-rTMS is indicated to be used 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.

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) Summary

General Information

Sponsor:	BTL Industries, Inc. 362 Elm Street Marlborough, MA 01752 Tel: +1-866-285-1656 Fax: +1-888-499-2502
Applicant:	BTL Industries, Inc. 362 Elm Street Marlborough, MA 01752 Tel: +1-866-285-1656 Fax: +1-888-499-2502
Contact Person:	David Chmel BTL Industries, Inc. chmel@btlnet.com
Summary Preparation Date:	February 1, 2022

Device Name

Trade/Proprietary Name:	BTL-995-rTMS
Primary Classification Name:	Transcranial Magnetic Stimulator
Classification Regulation:	882.5805, Class II
Classification Product Code:	OBP

Legally Marketed Predicate Device

The BTL-995-rTMS is a state-of-the-art device electromagnetic device with accessories and is substantially equivalent to the current product that is already cleared for distribution in the USA under the following 510(k) Premarket Notification number:

- MagVita TMS Therapy System (K150641)

Product Description

The BTL-995-rTMS is a non-invasive therapeutic device that produces and delivers magnetic field to induce electrical currents targeting specific regions of the human cerebral cortex.

BTL-995-rTMS consists of a main unit and applicator(s). The main unit consists of a master unit and a generator unit. The main unit is equipped with a color touch screen that makes the device easy to use. The on-screen information guides the Operator through the entire therapy procedure. The therapeutic parameters are easily set using the touch screen. During therapy, the screen displays information about the remaining therapy time and other therapy parameters.

The device functions with two applicator types: figure-of-8 coil applicator and circular coil applicator. The therapy is provided with the applicator attached to the applicator arm.

Indications for Use

BTL-995-rTMS is indicated to be used 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.

Clinical Testing

No clinical testing was performed for this device.

Non-clinical Testing (Performance, Bench Testing)

The BTL-995-rTMS device has been thoroughly evaluated for electrical safety. The device has been found to comply with the following applicable medical device safety standards:

IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62304	Medical device software – Software life cycle processes

ISO 14971	Medical devices – Application of risk management to medical devices
ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

Technological Characteristics

The BTL-995-rTMS device has the same intended use and principles of operation to its predicate device. The BTL-995-rTMS device and its predicate are comprised of a system console, arm for applicator positioning and applicator(s).

The mechanism of action and technological similarities and differences between the BTL-995-rTMS device and the predicate device are described below in the comparison table. The differences do not raise any new types of safety or effectiveness questions.

Comparison with the Predicate Device

510(k) number **Device name** **Company name**	**K212723** BTL-995-rTMS BTL Industries, Inc.	**K150641** MagVita TMS Therapy System Tonica Elektronik A/S
Product Code and Regulation	Neurology 21 CFR 882.5805 OBP - Transcranial Magnetic Stimulator	Neurology 21 CFR 882.5805 OBP - Transcranial Magnetic Stimulator
Indications for Use	BTL-995-rTMS is indicated to be used 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.	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.
Clinical use	Prescription use	Prescription use
Area of brain to be stimulated	Dorsolateral prefrontal cortex	Dorsolateral prefrontal cortex
Applicator: Configuration Core material	 biphasic air	 biphasic air

510(k) number **Device name** **Company name**	**K212723** BTL-995-rTMS BTL Industries, Inc.	**K150641** MagVita TMS Therapy System Tonica Elektronik A/S
Major Depressive Disorder	Magnetic Field Intensity: 120% of patient's measured hand Motor Threshold (MT).	Magnetic Field Intensity: 120% MT (MT=Motor Threshold intensity)
	Frequency: 10 Hz	Frequency:10 Hz
	Treatment train duration: 4 sec	Treatment train duration: 4 sec
	Inter-train interval: 11-26 sec	Inter-train interval: 26 sec
	Number of pulses administered per session: 3000	Number of pulses administered per session: 3000
Mobile console	yes	yes
System software with GUI	yes	yes
Coil positioning system	yes	yes
Cooling	Air cooled Used for both MT determination and treatment.	Liquid cooled Used for both MT determination and treatment.
Electrical safety	Complies with IEC60601-1 and IEC 60601-1-2	Complies with IEC60601-1 and IEC 60601-1-2

Substantial Equivalence

The BTL-995-rTMS device has the same intended use as its predicate device. The technological characteristics of the predicate device are similar to the BTL-995-rTMS device. Any differences between the predicate device and BTL-995-rTMS have no significant influence on safety and effectiveness of the BTL-995-rTMS device. Therefore, the BTL-995-rTMS is substantially equivalent to the predicate device.

Conclusion

Based upon the intended use and the known technical data provided in this pre-market notification, the BTL-995-rTMS device has been shown to be substantially equivalent to the currently marketed predicate device.