February 1, 2024

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

Re: K230657
Trade/Device Name: BTL-99-OC
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: February 20, 2023
Received: March 9, 2023

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 (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 Kang -S

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

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)*
K230657

Device Name
BTL-99-OC

Indications for Use *(Describe)*
BTL-99-OC 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
K230657

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:	30 January 2024

Device Name

Trade/Proprietary Name:	BTL-99-OC
Primary Classification Name:	Transcranial Magnetic Stimulation System For Obsessive-Compulsive Disorder
Classification Regulation:	882.5802, Class II
Classification Product Code:	QCI

Legally Marketed Predicate Device

The BTL-99-OC is a state-of-the-art 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 numbers:

- MagVenture TMS Therapy system – for treatment of OCD (K193006)

Reference device:

- BTL-995-rTMS (K212723)

Product Description

The BTL-99-OC 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-99-OC 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 set using the touch screen. During therapy, the screen displays information about the remaining therapy time and other therapy parameters.

The device functions with: M1 figure-of-8 coil applicator. The therapy is provided with the applicator attached to the applicator arm.

The BTL-99-OC composed of stimulation generator and stimulation coil. The stimulation generator is driven by software, which the operator controls through the GUI and contains a high voltage energy storage capacitor charging and discharging system, a power supply and a microcomputer control system. The software capabilities for administering treatment in the subject device are the comparable to these in the predicate devices. The stimulation coil is composed of a stimulation coil, an air forced cooling system and an applicator holder. The main unit BTL-99-OC with the M1 coil is intended to be used for both - MT threshold estimation and subsequent application of OCD therapy.

The BTL-99-OC is composed of:

- The main unit driven by software on chassis with 4 castors and with arm for coil positioning
- Stimulation Coil
    - Coil Figure-of-eight coil (M1 Coil)

Indications for Use

BTL-99-OC is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

Non-clinical Testing (Performance, Bench Testing)

The BTL-99-OC device has been thoroughly evaluated for electrical safety. The device has been found to comply with the following applicable medical device safety standards:

IEC 60601-1:2005+AMD1:2012+AMD2:2020

Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2: 2014+AMD1:2020

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: 2010+AMD1:2013

Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

IEC 62304:2006+A1:2015

Medical device software – Software life cycle processes

ISO 14971:2019

Medical devices – Application of risk management to medical devices

Biological evaluation of medical devices

Biological evaluation of the subject device is based on the equivalence of the materials used, which are the same as those used in the previously cleared reference device. BTL-99-OC and its M1 applicator (the patient contacting part) in its final finished form is identical to BTL-995-rTMS device and its M1 applicator [K212723] in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents, etc.)

Non-clinical Performance Testing

The subject device with M1 applicator and its technology remain identical to the device and its M1 applicator cleared under K212723. The proposed changes to BTL-99-OC, for adjunctive treatment of OCD, are limited to updates to the labelling and software to be possible use it safely and effectively as an adjunct treatment of OCD.
These changes were made to facilitate the safe and effective treatment of patients with OCD and do not raise any new or different questions of safety and effectiveness. All other aspects of the device remain unchanged and are identical to the currently cleared device, K212723.

Software verification & validation

The software V&V procedures were performed in accordance with IEC 62304 which is considered a well-established method used in the software development.

Device Performance verificationTests and measurements have been performed to verify that the subject device can operate reliably and safely even at maximum power while meeting the requirements of recognised international standards for electrical, mechanical, thermal safety, etc. Confirmed by test report according to international standard IEC 60601-1:2005+AMD1:2012+AMD2:2020

The subject device with M1 coil has a lower induced field strength when compared to the predicate device output intensity set to 100%. The subject device at its maximum 100% output intensity setting is substantially equivalent to the predicate device with its stimulation coil and output intensity set at 50%. Performance verification and comparison of the subject device and the predicate was made by the real data measurements of the induced fields on a phantom head (filled with saline) and by comparing the outputs from COMSOL Multiphysics simulations.

Performance testing of the coil parameters of the subject and predicate devices was performed The profiles and intensities of the induced fields (magnetic and electric) in the phantom head (filled with saline), in the different depths along the applicator central axis and planar measurements to obtain a 2D profiles of these fields at the different depths were taken at different distances (1-3cm) from the coil surface and these values were evaluated to determine substantial equivalency. For the same test scenarios described above, computer simulations were performed in COMSOL Multiphysics and the results were also compared.

As a result of this comparison, the values of the induced E-field intensities are substantially equivalent within the compared range and have average difference is in the range of +/-10% at distances of 1 to 3 cm from the coil surface.

The subject device has been tested and it conforms with the special controls set and requested in 21 CFR 882.5802 Transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions.

Technological Characteristics

The BTL-99-OC device has the same intended use and principles of operation to its predicate device. The BTL-99-OC 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-99-OC 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

	DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE
510(k) number	**K230657**	**K193006**	**K212723**
Device name	BTL-99-OC	MagVenture TMS Therapy – For Treatment Of OCD, MagVenture TMS Therapy System	BTL-995-rTMS
Company name	BTL Industries, Inc.	Tonica Elektronik A/S	BTL Industries, Inc.
Product Code and Regulation	Neurology 21 CFR 882.5802 QCI - Transcranial Magnetic Stimulation System for Obsessive-Compulsive Disorder	Neurology 21 CFR 882.5802 QCI - Transcranial Magnetic Stimulation System for Obsessive-Compulsive Disorder	Neurology 21 CFR 882.5805 OBP - Transcranial Magnetic Stimulator
Indications for Use	BTL-99-OC is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).	The MagVenture TMS Therapy System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).	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.

	DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE
510(k) number	**K230657**	**K193006**	**K212723**
Device name	BTL-99-OC	MagVenture TMS Therapy – For Treatment Of OCD, MagVenture TMS Therapy System	BTL-995-rTMS
Clinical use	Prescription use	Prescription use	Prescription use
Area of brain to be stimulated	Dorsomedial Prefrontal cortex	Dorsomedial prefrontal cortex	Dorsolateral prefrontal cortex
Applicator: Waveform Core material	 biphasic air	 biphasic air	 biphasic air
Treatment of:	Obsessive-Compulsive Disorder	Obsessive-Compulsive Disorder	Major depressive disorder
Therapy parameters	Magnetic Field Intensity: Not exceeding 100% of patient's measured Leg Motor Threshold (MT).	Magnetic Field Intensity: 100% of Leg MT (Leg Motor Threshold)	Magnetic Field Intensity: 120% of patient's measured hand Motor Threshold (MT).
	Frequency: 20 Hz (Up to 150Hz*)	Frequency: 20Hz	Frequency: 10Hz (Up to 150Hz)
	Treatment train duration: 2 sec (Up to 60s*)	Treatment train duration: 2 sec	Treatment train duration: 4 sec (Up to 60s)
	Inter-train interval: 20 sec	Inter-train interval: 20 sec	Inter-train interval: 11-26 sec

	DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE
510(k) number	**K230657**	**K193006**	**K212723**
Device name	BTL-99-OC	MagVenture TMS Therapy – For Treatment Of OCD, MagVenture TMS Therapy System	BTL-995-rTMS
	(Up to 120 s*)		(Up to 120 s)
	Number of trains: 50 (Up to 99*)	Number of trains: 50	Number of trains: 75 (Up to 99)
	Numbers of pulses: 2000 (Maximum depends on the combination of set parameters*)	Numbers of pulses: 2000	Numbers of pulses: 3000
	Total therapy duration: 18 min (Maximum depends on the combination of set parameters*)	Total therapy duration: 18 min	Total therapy duration: 19 - 37min
	Number of pulses administered per treatment: 58000 (Maximum depends on the combination of set parameters*)	Number of pulses administered per treatment: 58000	Number of pulses administered per treatment: 90000
Therapy sessions:	29	29	30

	DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE
510(k) number	**K230657**	**K193006**	**K212723**
Device name	BTL-99-OC	MagVenture TMS Therapy – For Treatment Of OCD, MagVenture TMS Therapy System	BTL-995-rTMS
	5 daily sessions for 5 weeks, and 4 daily session in the 6th week	5 daily sessions for 5 weeks, and 4 daily session in the 6th week	5 daily sessions for 6 weeks
Mobile console	yes	yes	Yes
System software with GUI	yes	yes	yes
Coil positioning system	yes	yes	yes
Cooling	Air cooled Used for both MT determination and treatment**.**	Liquid cooled Used for both MT determination and treatment**.**	Air cooled Used for both MT determination and treatment**.**
Temperature sensor	Yes, the system automatically reduces the output intensity of the device if the maximum temperature (41°C) of the parts in contact with the patient could be exceeded.	Not known	Yes, the system automatically reduces the output intensity of the device if the maximum temperature (41°C) of the parts in contact with the patient could be exceeded.
Coil parameters	M1 coil Type: Figure of 8 coil Inner diameter: 10 mm Outer diameter: 98 mm N = 2 wings 20 turns Core material: Air	D-B80 coil Type: Figure of 8 coil Inner diameter: 67 mm Outer diameter: 95 mm N = 2 wings 2 layers 4 & 3 turns Core material: Air	M1 coil Type: Figure of 8 coil Inner diameter: 10 mm Outer diameter: 98 mm N = 2 wings 20 turns Core material: Air

	DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE
510(k) number	**K230657**	**K193006**	**K212723**
Device name	BTL-99-OC	MagVenture TMS Therapy – For Treatment Of OCD, MagVenture TMS Therapy System	BTL-995-rTMS
Amplitude in Standard Motor Threshold (SMT) units (1 SMT is the output setting of a rTMS device that corresponds to an induced electric field of 130V/m at a point located at the fixed distance (3cm) of the target along the central axis of the coil measured with a pick-up loop)	0 – 1.5 SMT	0 - 3 SMT	0 – 1.5 SMT
Peak magnetic field strength at 2 cm	290 mT	230 mT	290 mT
Maximum dB/dt (on the applicator/scalp surface when 1.5SMT is set as target output intensity)	6 800 T/s	7 400 T/s	6 800 T/s
Electrical safety	Complies with IEC60601-1 and IEC 60601-1-2.	Complies with IEC60601-1 and IEC 60601-1-2.	Complies with IEC60601-1 and IEC 60601-1-2.

* Information marked with an asterisk is information about the maximum range/capabilities of the subject device,maximum parameters have not been cleared for treatment according to the cleared IFU of the subject device – they are not intended for use in the adjunct treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

Differences in maximum achievable amplitudes of SMT

Subject & Reference Devices: Intensity Setting = 0% → 0 SMT Intensity Setting = 100% → 1.5 SMT Predicate Device: Intensity Setting = 0% → 0 SMT Intensity Setting = 100% → 3 SMT (1 SMT is the output setting of a rTMS device that corresponds to an induced electric field of 130V/m at a point located at the fixed distance (3cm) of the target along the central axis of the coil measured with a pick-up loop)	The relationship between intensity setting and induced current in target distance is linear. Therefore, the presented comparison of SMT intensities between the subject and predicate device is possible: Subject device Intensity Setting corresponding to 100% = 1.5 SMT (output intensity at target distance) and consequently Predicate Device Intensity Setting corresponding to 50% = 1.5 SMT (output intensity at target distance) These values indicate the predicate device need a lower intensity setting to achieve the same level of induced current in the targeted tissue as the subject device. Although the value of the set intensity on the subject device looks visually higher compared the predicate (100% vs. 50%) it is an equivalent setting in terms of output stimulation parameters. It means in terms of the shape and intensity of the resulting electric and magnatic fields and therefore the intensity of the induced currents in the target tissue, since the achieved SMT values at this setting are substantially equivalent. In addition, identical coil specifications were used and cleared for the reference device coil and therefore, this difference does not affect the effectiveness or safety of the subject device.

Substantial Equivalence

The BTL-99-OC device has the same intended use as its predicate device. The technological characteristics of the predicate device are similar to the BTL-99-OC device.

The subject device is substantially equivalent to the predicate device in the comparable range of the set output intensity. Specifically, the subject device's range of 0-100%MSO (maximum stimulator output) at a distance of 3 cm in the central axis from the coil is equal to 0-1.5 SMT, which is equivalent to the predicate device's range of 0-50%MSO at a distance of 3 cm in the central axis from the coil is equal to 0-1.5 SMT.

An output setting in this 0-1.5 SMT range results in the substantially equivalent output performance and both devices have comparable intensities and profiles of induced electric and magnetic fields.

dB/dt values of the subject device compared to the predicate device measured on the scalp and at distance of 3 cm in the central axis from the coil when output intensities are set to 1.5SMT in both devices are comparable in their ratio 1.79:1 (6.8kT/s:3.8kT/s) and 1.95:1 (7.4kT/s:3.8kT/s)

The device can be considered clinically safe even at 100%MSO, when according to the measured data it generates 1.5SMT at a distance of 3 cm in the central axis from the coil, which is within the range of values achieved by the predicate device.

Any differences between the predicate device and BTL-99-OC have no significant influence on safety and effectiveness of the BTL-99-OC device. Therefore, the BTL-99-OC 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-99-OC device has been shown to be substantially equivalent to the currently marketed predicate device.