August 23, 2026

BTL Industries, Inc.
David Chmel
CEO North America
362 Elm St.
Marlborough, Massachusetts 01752

Re: K260691
Trade/Device Name: BTL-699
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive transcranial magnetic stimulation system
Regulatory Class: Class II
Product Code: OBP, QCI
Dated: July 22, 2026
Received: July 22, 2026

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 D. Scott
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260691

Please provide the device trade name(s).

BTL-699

Please provide your Indications for Use below.

The BTL-699 is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder (MDD) and who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.
The BTL-699 is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).
The BTL-699 is indicated as an adjunct for the treatment of Major Depressive Disorder in adolescent patients (age 15-21).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
K260691

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:	22 August 2026

Device

Trade/Proprietary Name:	BTL-699
Primary Classification Name:	Transcranial Magnetic Stimulator, Transcranial Magnetic Stimulation System for Obsessive-Compulsive Disorder
Classification Regulation:	21 CFR 882.5805 and 882.5802, Class II
Classification Product Code:	OBP, QCI

Legally Marketed Predicate Device

The BTL-699 is a state-of-the-art electromagnetic device with accessories, and is substantially equivalent to the following products that are already cleared for distribution in the USA under the following 510(k) Premarket Notification numbers:

For treatment of Major Depressive Disorder (MDD) with comorbid anxiety symptoms, and an adjunct treatment of Obsessive-Compulsive Disorder (OCD) in adult patients.

Primary predicate device:
MagVenture TMS Therapy System
510(k) Number: K251119
Original 510(k) Sponsor: Tonica Elektronik A/S

Secondary predicate device:
BTL-995-rTMS
510(k) Number: K212723
Original 510(k) Sponsor: BTL Industries, Inc.

Secondary predicate device:
BTL-99-OC
510(k) Number: K230657
Original 510(k) Sponsor: BTL Industries, Inc.

Third precicate device:

NeuroStar Advanced Therapy System
510(k) Number: K233621
Original 510(k) Sponsor: Neuronetics, Inc.

For treatment of adjunct Major Depressive Disorder in adolescent patients (age 15-21).

Primary predicate device:
MagVenture TMS Therapy System
510(k) Number: K251125
Original 510(k) Sponsor: Tonica Elektronik A/S

Product Description

The BTL-699 is a non-invasive therapeutic device that generates and delivers magnetic field to induce electrical currents in targeted areas of the human cerebral cortex.

The BTL-699 consists of the main unit and applicator system. The main unit is equipped with a color touch screen with a wide view angle, enabling intuitive and easy operation. On-screen information guides the operator through the entire therapy procedure. Therapeutic parameters are set using the touch screen and control buttons on the device. During therapy, the screen displays information regarding the applied therapy type, the remaining therapy time, and other relevant therapy parameters.

The BTL-699 is equipped with an applicator, an applicator arm for precise positioning, a headrest with fixation belt, and a therapy discomfort button. The stimulation coil is designed with an air-forced cooling system.

Indications for Use

The BTL-699 is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive

Disorder (MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode.

The BTL-699 is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).

The BTL-699 is indicated as an adjunct for the treatment of Major Depressive Disorder in adolescent patients (age 15-21).

Non-clinical Testing

Nonclinical testing was conducted to evaluate the performance of the BTL-699 device and demonstrated equivalence in terms of safety and effectiveness as compared to the predicate device.

Bench testing conducted to support substantial equivalence can be divided into two categories:

(1) safety testing, including compliance with applicable ISO and IEC standards for

- biocompatibility, electrical safety and electromagnetic compatibility (EMC), and

(2) performance testing, including evaluation of electromagnetic output characteristics.

The device has been found to comply with 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 TS 60601-4-2:2024

Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

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

ISO 10993-1:2018

Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

ISO 10993-5:2009

Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2021

Biological evaluation of medical devices - Part 10: Tests for skin sensitization

ISO 10993-23:2021

Biological evaluation of medical devices - Part 23: Tests for irritation

The contents of this 510(k) submission and the device labeling have been prepared with respect to the requirements and recommendations set forth in the FDA Guidance Document entitled *"Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems – Guidance for Industry and Food and Drug Administration Staff."*

Clinical Testing

Not applicable to this submission. The subject device is substantially equivalent to the predicate devices. The subject device has the same indications for use and substantially equivalent technological characteristics, including device specifications and output parameters, as the predicate devices. Therefore, in accordance with the substantial equivalence determination principles, clinical data are not required to support this submission.

Technological characteristics

The BTL-699 device has the same intended use and technological characteristics compared to its predicate devices. The BTL-699 device and the predicates are comprised of a mobile console, system software with GUI and coil positioning system.

Comparison with the Predicate and Reference Devices

In this 510(k) submission, the indications for use of the subject device are being expanded based on a comparison with multiple predicate devices that share the same technology, operational procedures, and principles. For this reason, multiple substantial equivalence comparison tables (Table A and B) are provided below, with each table discussing substantial equivalence to a specific predicate device and its respective indications for use.

In the tables below, the MagVenture TMS Therapy System is used as the primary predicate for comparison regarding the expansion of the device's indications: in Table A, for decreasing anxiety symptoms in adult patients suffering from Major Depressive Disorder who exhibit comorbid anxiety symptoms, and in Table B, for expanding the patient population for MDD therapy to include adolescents (aged 15–21 years).

The secondary predicate devices, BTL-99-OC and BTL-995-rTMS, cleared for Major Depressive Disorder (MDD) and Obsessive-Compulsive Disorder (OCD) indications in adult patients, are included in Table A.

A) BTL-699 for treatment of Major Depressive Disorder w/ Comorbid Anxiety Symptoms (OBP) and Obsessive-Compulsive Disorder (QCI)

510(k) No. **Device name** **Company name**	**K260691** **BTL-699** **BTL Industries, Inc.**	**K251119** **MagVenture TMS Therapy System** **Tonica Elektronik A/S.**	**K212723** **BTL-995-rTMS** **BTL Industries, Inc.**	**K230657** **BTL-99-OC** **BTL Industries, Inc.**	**K233621** **NeuroStar Advanced Therapy System** **Neuronetics, Inc.**
Type	Subject device	Primary predicate device	Secondary predicate device	Secondary predicate device	Third predicate device
Product Code and Regulation	Neurology 21 CFR 882.5805 and 882.5802 OBP - Repetitive transcranial magnetic stimulation system QCI - Transcranial Magnetic Stimulation System for Obsessive-Compulsive Disorder	Neurology 21 CFR 882.5805 and 882.5802 OBP - Repetitive transcranial magnetic stimulation system QCI - Transcranial Magnetic Stimulation System for Obsessive-Compulsive Disorder	Neurology 21 CFR 882.5805 OBP - Repetitive transcranial magnetic stimulation system	Neurology 21 CFR 882.5802 QCI - Transcranial Magnetic Stimulation System for Obsessive-Compulsive Disorder	Neurology 21 CFR 882.5805 and 882.5802 OBP - Repetitive transcranial magnetic stimulation system QCI - Transcranial Magnetic Stimulation System for Obsessive-Compulsive Disorder
Indications for Use	The BTL-699 is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder	The MagVenture TMS Therapy System is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder	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	BTL-99-OC is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).	The NeuroStar Advanced Therapy System is indicated for the treatment of depressive episodes and for decreasing anxiety symptoms for those who may exhibit comorbid anxiety symptoms in adult patients suffering from Major Depressive Disorder

	(MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode. The BTL-699 is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).	(MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode. 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).	medication in the current episode.		(MDD) and who failed to achieve satisfactory improvement from previous antidepressant medication treatment in the current episode. The NeuroStar Advanced Therapy System is intended to be used as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD).
Clinical Use	Prescription use	Prescription use	Prescription use	Prescription use	Prescription use
Area of brain to be stimulated	Left dorsolateral prefrontal cortex (MDD) Dorsomedial prefrontal cortex (OCD)	Left dorsolateral prefrontal cortex (MDD) Dorsomedial prefrontal cortex (OCD)	Left dorsolateral prefrontal cortex	Dorsomedial prefrontal cortex	Left dorsolateral prefrontal cortex (MDD) Dorsomedial prefrontal cortex (OCD)
Target Population	Adult Patients	Adult Patients	Adult Patients	Adult Patients	Adult Patients
Technical Parameters					
Coil Type	Figure-of-eight coil with an air core	Figure-of-eight coil with a ferromagnetic core	Figure-of-eight coil with an air core		Figure-of-eight coil with a ferromagnetic core
Pulse Type	Biphasic	Biphasic	Biphasic		Biphasic
Pulse Width	220 – 330 µs	290 µs (±5%)	362 µs (±20%)		185 µs (±10%)
Mobile Console	Yes	Yes	Yes		Yes
System Software with	Yes	Yes	Yes		Yes

GUI				
Coil Positioning	Yes	Yes	Yes	Yes
Cooling	Air cooled	Forced liquid cooling	Air cooled	Air cooled
Electrical safety & Electro-magnetic Compatibility	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	Complies with IEC60601-1 and IEC 60601-1-2
Frequency range (Hz)	0 – 150	0 – 100	0 – 150	0 – 30
Preset range of % MT	50 – 140	0 – 140	50 – 200	25 – 140
Pulse train duration range (sec)	0 – 30	1 – 33	0 – 60	1 – 20
Inter-train interval range (sec)	0 – 30	10 – 120	0 – 120	10 – 60
Available Stimulation Intensity in terms of Standard Motor Threshold (SMT) units	0 – 1.8 SMT	0 – 1.9 SMT	0 – 1.5 SMT	0.22 – 2.08 SMT
Peak magnetic field strength (T) at a depth of 2 cm	0.31 T	0.5 T	0.29 T	0.28 T

Peak magnetic field strength (T) at a depth of 3 cm	0.24 T	0.40 T	0.23 T		0.18 T
Peak magnetic field gradient dB/dt (kT/s) at a depth of 2 cm	7 kT/s	10.5 kT/s	6.8 kT/s		9.7 kT/s
Peak magnetic field gradient dB/dt (kT/s) at a depth of 3 cm	5.4 kT/s	8.7 kT/s	4 kT/s		5.8 kT/s
Scalp : 3 cm depth peak magnetic field gradient dB/dt (kT/s) ratio	1,9	1,6	1,8		3
Treatment Parameters – Protocol – MDD w/ Comorbid Anxiety Symptoms					
Magnetic Field Intensity	120% of MT with allowable adjustments downwards only	120% of MT	120% of MT	N/A	120% of MT
Frequency	10 Hz	10 Hz	10 Hz	N/A	10 Hz
Therapy Train Duration	4 s	4 s	4 s	N/A	4 s
Inter-train Interval	11 – 26 s	11 – 26 s	11 – 26 s	N/A	11 – 26 s

Therapy Duration	18.75 – 37.5 min	19 - 37.5 min	18.75 - 37.5 min	N/A	18.75 - 37.5 min
Pulses per Session	3 000	3 000	3 000	N/A	3 000
Treatment Parameters – Protocol – OCD					
Magnetic Field Intensity	100% foot motor threshold level	100% foot motor threshold level	N/A	100% foot motor threshold level	100% of MT (Tibialis Motor Cortex)
Frequency	20 Hz	20 Hz	N/A	20 Hz	20 Hz
Therapy Train Duration	2 s	2 s	N/A	2 s	2 s
Inter-train Interval	20 s	20 s	N/A	20 s	20 s
Therapy Duration	18.3 min	18.3 min	N/A	18.3 min	18.3 min
Pulses per Session	2 000	2 000	N/A	2 000	2 000
Treatment Parameters – Protocol – iTBS Mode					
Magnetic Field Intensity	120% MT with allowable adjustments downwards only	120% MT with allowable adjustments	N/A	N/A	120% MT with allowable adjustments
Pulses per Burst	3	3	N/A	N/A	3
Pulses Frequency	50 Hz	50 Hz	N/A	N/A	50 Hz
Burst	5 Hz	5 Hz	N/A	N/A	5 Hz

Frequency					
Train Duration	2 s	2 s	N/A	N/A	2 s
Therapy Duration	3.3 min	3.3 min	N/A	N/A	3.15 min
Inter-train Interval	8 s	8 s	N/A	N/A	8 s
Pulses per Session	600	600	N/A	N/A	600

Substantial Equivalence Discussion

The table A) above (product codes OBP and QCI) compares the BTL-699 device to the identified predicate device, MagVenture TMS Therapy System (K251119), with respect to indications for use and technological characteristics, including principles of operation, device design, and output stimulation parameters. These comparisons provide the basis for the determination of substantial equivalence.

The subject device has the same indications for use as the predicate device. Both devices are indicated to deliver transcranial magnetic stimulation (TMS) therapy at a defined intensity using repetitive pulse trains composed of brief, rapidly alternating magnetic fields that induce electrical currents in targeted cortical areas.

The operational procedures for both devices are substantially equivalent and include system setup, patient preparation, motor threshold determination, coil positioning, and patient treatment using predefined stimulation parameters. Both devices target the same anatomical region of the brain.

A combination of primary, secondary, and third predicate devices was used to demonstrate the substantial equivalence of the subject device to the predicate devices. Secondary predicates are presented in the comparison table to reference previously cleared devices from the same manufacturer for the part of indications for use, which are the therapy of MDD and OCD in the adult population. The primary predicate is used to compare a legally marketed device with extended indications to include therapy for decreasing of anxiety symptoms for MDD with comorbid anxiety symptoms. The third predicate is referenced to demonstrate comparable field intensities achieved in deeper cortical layers for the requested OCD indication.

To demonstrate substantial equivalence of the subject device in terms of adequate safety and effectiveness for the treatment of OCD, performance testing of the subject device and a comparison of its magnetic and electric field profiles were provided. Although the maximum magnetic field intensity at a 3 cm depth of the subject device does not reach the values of its primary predicate device, the MagVenture TMS Therapy System (K251119), its performance profile and maximum intensity values at a 3 cm depth are comparable to the secondary and third predicate devices, namely the BTL-99-OC (K230657) and NeuroStar Advanced Therapy System (K233621). Furthermore, the magnetic field gradient, dB/dt (kT/s), and the scalp-to-3-cm-depth ratio remain within the range established by these predicate devices.

The comparison of the subject and predicate devices is based on bench testing and a detailed comparison of their electromagnetic fields. Performance testing, including comprehensive electromagnetic field mapping, demonstrates that the field characteristics of the subject device are comparable to those of the predicate devices. Therefore, the subject device is substantially equivalent to the predicate devices and do not raise new or modified questions of safety or effectiveness.

The differences in the general technical parameters (capabilities) of the devices, such as pulse width, settable train and inter-train ranges, the maximum available operating frequency, the maximum available output intensity are attributable to variations in technical design. Since the parameters of the therapeutic protocol are identical for the subject and predicate devices, and the intensity of the delivered therapy is always determined individually based on the excitability of the specific patient, these differences do not raise new or different questions of safety and effectiveness, nor do they have a significant impact on the safety or therapeutic effectiveness of the subject device.

Any differences between the predicate device and the BTL-699 device do not raise different questions of safety and effectiveness. Therefore, the BTL-699 device is substantially equivalent to the predicate device.

B) BTL-699 for treatment of adjunct Major Depressive Disorder in adolescent patients (age 15-21)

510(k) No. **Device name** **Company name**	**K260691** **BTL-699** **BTL Industries, Inc.**	**K251125** **MagVenture TMS Therapy System** **Tonica Elektronik A/S**
Type	Subject device	Predicate device
Product Code and Regulation	Neurology 21 CFR 882.5805 OBP - Repetitive transcranial magnetic stimulation system	Neurology 21 CFR 882.5805 OBP - Repetitive transcranial magnetic stimulation system
Indications for Use	The BTL-699 is indicated as an adjunct for the treatment of Major Depressive Disorder in adolescent patients (age 15-21).	MagVenture TMS Therapy System is indicated as an adjunct for the treatment of Major Depressive Disorder in adolescent patients (age 15-21).
Clinical Use	Prescription use	Prescription use
Area of brain to be stimulated	Left dorsolateral prefrontal cortex	Left dorsolateral prefrontal cortex
Target populations	Adolescent patients aged 15-21 years	Adolescent patients aged 15-21 years
Technical Parameters		
Coil Type	Figure-of-eight coil with an air core	Figure-of-eight design with dual windings and an air core
Pulse Type	Biphasic	Biphasic
Pulse Width	220 – 330 µs	290 µs (±5%)
Mobile Console	Yes	Yes
System Software with GUI	Yes	Yes

Coil Positioning	Yes	Yes
Cooling	Air cooled	Forced liquid cooling
Electrical safety	Complies with IEC60601-1 and IEC 60601-1-2	Complies with IEC60601-1 and IEC 60601-1-2
Frequency range (Hz)	0 – 150	0 – 100
Preset range of % MT	50 – 140	0 – 140
Available Stimulation Intensity in terms of Standard Motor Threshold (SMT) units	0 – 1.8 SMT	0 – 1.7 SMT
Treatment Parameters – MDD (Adolescents age 15-21)		
Magnetic Field Intensity	120% of MT	120% of MT
Frequency	10 Hz	10 Hz
Therapy Train Duration	4 s	4 s
Inter-train Interval	11 – 26 s	11 – 26 s
Therapy Duration	18.75 – 37.5 min	19 - 37.5 min
Pulses per Session	3 000	3 000
Treatment Parameters – iTBS Mode – (Adolescents age 15-21)		
Magnetic Field Intensity	120% MT	120% MT
Pulses per Burst	3	3

Pulses Frequency	50 Hz	50 Hz
Bursts	200	200
Train Duration	2 s	2 s
Therapy Duration	3.3 min	3.3 min
Inter-train Interval	8 s	8 s
Interpulse interval	20 msec	20 msec
Number of trains	20	20
Pulses per Session	600	600

Substantial Equivalence Discussion

The table B) above (product code OBP) compares the BTL-699 device to the identified predicate device, MagVenture TMS Therapy System (K251125), with respect to indications for use and technological characteristics, including principles of operation, device design, and output stimulation parameters. These comparisons provide the basis for the determination of substantial equivalence.

The subject device has the same indications for use as the predicate device. Both devices are indicated to deliver transcranial magnetic stimulation (TMS) therapy at a defined intensity using repetitive pulse trains composed of brief, rapidly alternating magnetic fields that induce electrical currents in targeted cortical areas.

The operational procedures for both devices are substantially equivalent and include system setup, patient preparation, motor threshold determination, coil positioning, and patient treatment using predefined stimulation parameters. Both devices target the same anatomical region of the brain.

Based on the detailed electromagnetic field mapping and comparison of both the electric and magnetic fields generated by the subject and predicate device, it can be concluded that the resulting stimulation field profiles in targeted tissue of the subject and predicate devices are substantially equivalent. And, no new or different risks are introduced in comparison to the predicate device.

The differences in the general technical parameters (capabilities) of the devices, such as pulse width, settable train range, inter-train range, the maximum available operating frequency, the maximum available output intensity are attributable to variations in technical design. Since the parameters of the therapeutic protocol are identical for both the subject and predicate devices, and the intensity of the delivered therapy is always determined individually based on the excitability of the specific patient, these differences do not raise new or different questions of safety and effectiveness, nor do they have a significant impact on the safety or therapeutic effectiveness of the subject device.

Substantial Equivalence

The BTL-699 device has the same intended use as its predicate devices. The technological characteristics of the predicate devices are comparable to the BTL-699 device. Performance testing, including comprehensive mapping of both electric and magnetic fields, demonstrates that the electromagnetic field characteristics of the subject device are comparable to those of the predicate devices. Any differences between the predicate devices and BTL-699 have no significant influence on safety and effectiveness of the device. Therefore, the BTL-699 is substantially equivalent to the predicate devices.

Conclusion

Based upon the intended use and known technical information provided in this pre-market notification, the BTL-699 device and its accessories have been shown to be substantially equivalent to currently marketed predicate devices MagVenture TMS Therapy System (K251119 and K251125), BTL-995-rTMS (K212723), and BTL-99-OC (K230657).