July 5, 2019

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

Re: K190456
Trade/Device Name: BTL 799-2L
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: April 4, 2019
Received: April 9, 2019

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,

Vivek Pinto, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190456

Device Name
BTL 799-2L

Indications for Use *(Describe)*
BTL 799-2L is indicated to be used for:
• Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen.
• Strengthening, Toning and Firming of buttocks, thighs and calves.
• Improvement of muscle tone and firmness, for strengthening muscles in arms.

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

K190456

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:	June 28, 2019

Device Name

Trade/Proprietary Name:	BTL 799-2L
Primary Classification Name:	Stimulator, Muscle, Powered
Classification Regulation:	21 CFR 890.5850, Class II
Classification Product Code:	NGX

Legally Marketed Predicate Device

The BTL 799-2L is a state-of-the-art electromagnetic device with accessories, and is substantially equivalent to the current products that are already cleared for distribution in the USA under the following 510(k) Premarket Notification number:

- primary predicate 799-2T (K182106)

- secondary predicate HPM-6000 (K160992)

Product Description

The BTL 799-2L is a non-invasive therapeutic device. The device produces electromagnetic field that interacts with the tissues of the human body. The device has two outputs that enable simultaneous treatment by two applicators.

The BTL 799-2L is equipped with a large color touch screen with wide view angle that significantly facilitates the use of the device. The on-screen information guides the user step-by-step through the entire therapy procedure. The therapeutic parameters are easily set using the touch screen of the device. During the therapy the device keeps information about the applied therapy type, remaining therapy time and main therapy parameters on the screen.

Intended Use

BTL 799-2L is indicated to be used for:

- Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen.
- Strengthening, Toning and Firming of buttocks, thighs and calves.
- Improvement of muscle tone and firmness, for strengthening muscles in arms.

Non-clinical Testing

The BTL 799-2L 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 60601-2-10	Medical Electrical Equipment – Part 2-10: Particular Requirements for the Basic Safety and Essential Performance of Nerve and Muscle Stimulators
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 799-2L device has similar indications for use, technological characteristics and principles of operation to its predicate devices. The BTL 799-2L device and its predicates are comprised of a system console and applicator(s). The system console consists of the electromagnetic field generators, computer, and the touch-screen control panel.

Generated electromagnetic field is intended to interact with the tissues of the human body to achieve muscle stimulation.

The technological similarities and differences between the BTL 799-2L device and predicate devices 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**	**K190456** BTL 799-2L BTL Industries, Inc.	**K182106** BTL 799-2T BTL Industries, Inc.	**K160992** HPM-6000 BTL Industries, Inc.
Product Code and Regulation	Physical Medicine 21 CFR 890.5850 NGX – Stimulator, Muscle, Powered, Muscle Conditioning	Physical Medicine 21 CFR 890.5850 NGX – Stimulator, Muscle, Powered, Muscle Conditioning	Physical Medicine 21 CFR 890.5850 IPF - Stimulator, Muscle, Powered
Intended Use	BTL 799-2L is indicated to be used for: • Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen. • Strengthening, Toning and	BTL 799-2T is indicated to be used for: • Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen. • Strengthening, Toning and	Indications for Use for Muscle Stimulators: • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle re-education

510(k) number Device name Company name	K190456 BTL 799-2L BTL Industries, Inc.	K182106 BTL 799-2T BTL Industries, Inc.	K160992 HPM-6000 BTL Industries, Inc.
	Firming of buttocks, thighs and calves. • Improvement of muscle tone and firmness, for strengthening muscles in arms.	Firming of buttocks and thighs. • Improvement of muscle tone and firmness, for strengthening muscles in arms.	• Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Maintaining or increasing range of motion
Principle of Action	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction
Clinical Use	Prescription use	Prescription use	Prescription use
Electrical Protection	Class II, BF	Class II, BF	Class II, BF
User Interface	Touch screen	Touch screen	Touch screen
Firmware Controlled	Yes	Yes	Yes
Type of Energy	Magnetic field	Magnetic field	Magnetic field
Number of outputs	2	2	1
Number of Magnetic Coils in the Applicator	1	1	1
Magnetic Field Intensity	BTL 299-6 applicator: 0.5 - 1.8 T ±20%	BTL 299-6 applicator: 0.5 - 1.8 T ±20%	BTL 299-1 applicator: 0.5 - 1.8 T ±20%
	BTL 299-7 applicator: 0.7 - 2.0 T ±20%	N/A	BTL 299-2 applicator: 0.7 - 2.5 T ±20%
Maximum Magnetic Field Intensity at Applicator Center Surface	BTL 299-6 applicator: 1.154 T ±20%	BTL 299-6 applicator: 1.154 T ±20%	BTL 299-1 applicator: 1.220 T ±20%
	BTL 299-7 applicator: 1.173 T ±20%	N/A	BTL 299-2 applicator: 1.412 T ±20%
Pulse Repetition Rate	1 – 150 Hz	1 – 150 Hz	1 – 150 Hz

510(k) number Device name Company name	K190456 BTL 799-2L BTL Industries, Inc.	K182106 BTL 799-2T BTL Industries, Inc.	K160992 HPM-6000 BTL Industries, Inc.
Pulse Duration	BTL 299-6 applicator: 280 ± 20% µs	BTL 299-6 applicator: 280 ± 20% µs	BTL 299-1 applicator: 280 ± 20% µs
	BTL 299-7 applicator: 190 ± 20% µs	N/A	BTL 299-2 applicator: 280 ± 20% µs
Selection of parameters (Intensity, Time)	Yes	Yes	Yes
Therapy Time	Up to 60 min	Up to 60 min	Up to 60 min
Energy Source	100 – 240 V AC, 50–60 Hz	100 – 240 V AC, 50–60 Hz	100 – 240 V AC, 50–60 Hz
System Dimensions (W×H×D)	580×1380×580 mm (23×55×23 in)	580×1380×580 mm (23×55×23 in)	500×970×580 mm (20×38×23 in)
Ambient Temperature	-10°C to +55°C	-10°C to +55°C	-10°C to +55°C
Relative Humidity	10% to 85%	10% to 85%	10% to 85%
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only

Substantial Equivalence

The BTL 799-2L device is intended for improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen; strengthening, toning and firming of buttocks and thighs; improvement of muscle tone and firmness, for strengthening muscles in arms, identically compared to the primary predicate device. Additionally, the BTL 799-2L device is intended for calves strengthening, toning and firming, which is supported by the secondary predicate device HPM-6000.

The BTL 799-2L, when compared to the primary predicate device, may be used with two types of applicators. Applicator BTL 299-6 is identical to the applicator of the primary predicate device. The new applicator BTL 299-7 is of smaller size on the ground that it is intended to be used for smaller treatment areas, such as calves.

The BTL 299-7 applicator has slightly higher magnetic field intensity and shorter pulse width when compared to the applicator of the primary predicate device. However, magnetic field

intensity is within the range of the BTL 299-2 applicator of the second predicate device. Pulse duration is shorter due to the smaller coil surface intended for smaller muscle parts.

The applicator of the primary predicate device (BTL 299-6) has wider field exposure compared to the currently submitted BTL 299-7 applicator. This is because the BTL 299-7 coil is smaller than the one in the BTL 299-6 applicator, due to the fact that the BTL 299-6 applicator is intended for larger groups of muscles, while the new BTL 299-7 applicator is intended for smaller muscle parts, particularly arms and calves.

All named applicators are based on identical principle, mechanism of action, as well as manufacturing material. The system console, consisting of the electromagnetic field generators, computer, and the touch-screen control panel is also identical to the predicate devices.

Any differences between the predicate devices and BTL 799-2L device have no significant influence on safety or effectiveness of the BTL 799-2L device. Therefore, the BTL 799-2L device 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 799-2L device has been shown to be substantially equivalent to currently marketed predicate devices.