January 6, 2021

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

Re: K200382
Trade/Device Name: BTL-703-2
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: December 10, 2020
Received: December 14, 2020

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,

Amber Ballard, 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)*
K200382

Device Name
BTL-703-2

Indications for Use *(Describe)*
BTL-703-2 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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:	31 December 2020

Device Name

Trade/Proprietary Name:	BTL-703-2
Primary Classification Name:	Stimulator, Muscle, Powered, Muscle Conditioning
Classification Regulation:	21 CFR 890.5850, Class II
Classification Product Code:	NGX

Legally Marketed Predicate Device

The BTL-703-2 is a state-of-the-art device with accessories combining electromagnetic and high frequency energy, and is substantially equivalent to the following product, which is already cleared for distribution in the USA under the following 510(k) Premarket Notification number:

- 799-2L (K190456)

Reference Device BTL-899
The reference device has been added to this section because it is technologically similar to the BTL-703-2 device. Both devices are tracked internally under a common project number, P899. Hence, all test reports and technical documentation refer to this number.

Product Description

The BTL-703-2 is a non-invasive therapeutic device. The device is comprised of a main unit and applicators that deliver electromagnetic and radiofrequency energy to the targeted tissue. The device's two outputs enable hands-free simultaneous treatment by two applicators.

The BTL-703-2 is equipped with a large color touch-screen 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.

Indications for Use

BTL-703-2 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-703-2 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 62304	Medical device software – Software lifecycle 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-703-2 device has similar indications for use and technological characteristics and principles of operation to its predicate device. The BTL-703-2 device and its predicate are comprised of a system console and applicators. The system console consists of the electromagnetic field and radiofrequency generators, computer, and a touch-screen control panel.

The generated electromagnetic field is intended to interact with the tissues of the human body in order to achieve muscle stimulation. The radiofrequency is providing a low degree of warming of the applicators and thus enhance the patient’s comfort during the treatment.

The mechanism of action and technological similarities and differences between the BTL-703-2 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 Devices

510(k) number **Device name** **Company name**	**K200382** BTL-703-2 BTL Industries, Inc.	**K190456** BTL 799-2L BTL Industries, Inc.	**Reference Device** **K192224** BTL-899 BTL Industries, Inc.	**Significant difference**
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	General & Plastic Surgery 21 CFR 878.4400 GEI - Electrosurgical, Cutting & Coagulation & Accessories	**None**
Indications for Use	BTL-703-2 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.	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.	BTL-899 is indicated to be used for: - Non-invasive lipolysis (breakdown of fat) of the abdomen. - Reduction in circumference of the abdomen The BTL-899 is intended for use with Skin Type I to Skin Type III.	**Not Significantly different**
Basic Technology	Electromagnetic stimulation accompanied by bipolar radiofrequency	Electromagnetic stimulation	Electromagnetic stimulation accompanied by bipolar radiofrequency	**Not Significantly different** Please see the discussion and

				conclusion below
Clinical Use	Prescription use	Prescription use	Prescription use	**None**
Electrical Protection	Class II, BF	Class II, BF	Class II, BF	**None**
User Interface	Touch screen	Touch screen	Touch screen	**None**
Firmware Controlled	Yes	Yes	Yes	**None**
Number of outputs channels	2	2	2	**Not Significantly different**
Number of output modes*	1	1	1	**None**
Number of Magnetic coils in the Applicator	1	1	1	**None**
Magnetic Field Intensity (on the coil surface)	0.5 to 1.8 T for app: BTL-899-AP-C-1	0.5 to 1.8 T for app: BTL 299-6	0.5 to 1.8 T for app: BTL-899-AP-C-1	**None**
Magnetic Field Intensity (on the coil surface)	0.7 to 2.0 T for app: BTL-899-AP-C-2	0.7 to 2.0 T for app: BTL 299-7	N/A	**None**
Maximum magnetic	908 mT	980 mT	908 mT	**None**

field intensity at applicator center surface	for app: BTL-899-AP-C-1	for app: BTL 299-6	for app: BTL-899-AP-C-1	
Maximum magnetic field intensity at applicator center surface	1238 mT for app: BTL-899-AP-C-2	1220 mT for app: BTL 299-7	1238 mT	**None**
Pulse Repetition Rate - supported by the device	1 – 150 Hz	1 – 150 Hz	1 – 150 Hz	**None**
Pulse Duration	280 µs ± 20% µs for app: BTL-899-AP-C-1	280 µs ± 20% µs for app: BTL 299-6	280 µs ± 20% µs for app: BTL-899-AP-C-1	**None**
Pulse Duration	190 µs ± 20% µs for app: BTL-899-AP-C-2	190 µs ± 20% µs for app: BTL 299-7	N/A	**None**
Waveform	Biphasic	Biphasic	Biphasic	**None**
Shape	Sinusoidal	Sinusoidal	Sinusoidal	**None**
RF Type	Bipolar	N/A	Bipolar	**Not Significantly different** Please see discussion on basic technology below

Total RF Power	60 W (2x30)	N/A	60 W (2x30)	**Not Significantly different** Please see discussion on basic technology below
RF Frequency	27.12 Mhz	N/A	27.12 Mhz	**Not Significantly different** Please see discussion on basic technology below
Overheating Protection Sensor	Yes	N/A	Yes	**Not Significantly different**
Selection of parameters	Yes	Yes	Yes	**None**
Application	Hands-free, applicator fixed by fixation belt	Hands-free, applicator fixed by fixation belt	Hands-free, applicator fixed by fixation belt	**Not Significantly different**
Therapy Time	Up to 30 min	Up to 60 min	Up to 30 min	**Not Significantly different**
Energy Source	100 – 240 V AC, 50–60 Hz	100 – 240 V AC, 50–60 Hz	100 – 240 V AC, 50–60 Hz	**None**
Maximum Output Voltage	N/A	N/A	N/A	N/A
Maximum Output Current	N/A	N/A	N/A	N/A
Maximum Current Density **(mA/cm²)**	N/A	N/A	N/A	N/A

Maximum Phase Charge, (mC)	N/A	N/A	N/A	N/A
Maximum Power Density* (W/cm²)	N/A	N/A	N/A	N/A
System Dimensions (W×H×D)	23 x 39 x 29 in (592 x 985 x 730 mm)	23 × 55 × 23 in (580×1380×580 mm)	23 x 39 x 29 in (592 x 985 x 730 mm)	**Not Significantly different**
System Weight	85 kg	44 kg	85 kg	**Not Significantly different**
Ambient Storage Temperature	14 °F to 131 °F (-10°C to +55°C)	14 °F to 131 °F (-10°C to +55°C)	14 °F to 131 °F (-10°C to +55°C)	**None**
Relative Storage Humidity	10% to 85%	10% to 85%	10% to 85%	**None**
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	**None**

Substantial Equivalence

The BTL-703-2 is indicated for improvement of abdominal tone, strengthening of the abdominal muscles and development of firmer abdomen, as well as for strengthening, toning and firming of buttocks, thighs and calves. These indications are the same as the predicate device's indications.

The predicate device BTL-799L utilizes electromagnetic stimulation in order to achieve therapeutic effect. The proposed device BTL-703-2 also utilizes electromagnetic stimulation for its main therapeutic effect; however, the device is also equipped with a bipolar radiofrequency generator. The radiofrequency is warming the applicators' surface to below 40°C thus enhancing the patient's comfort during the treatment.

The BTL-703-2 electromagnetic technology is identical to FDA cleared predicate device BTL 799-2L. The bipolar radiofrequency technology has also been cleared by FDA in a number of devices, for example BTL-899 (K192224).

Any differences between the predicate device and BTL-703-2 have no significant influence on the safety or effectiveness of the BTL-703-2 device. Therefore, the BTL-703-2 is substantially equivalent to the predicate device.

Conclusion

Based upon the intended use and known technical information provided in this pre-market notification, the BTL-703-2 device has been shown to be substantially equivalent to the currently marketed predicate devices.