December 26, 2023

BTL Industries, Inc
David Chmel
Official Correspondent
362 Elm Street
Marlborough, Massachusetts 01752

Re: K232937
Trade/Device Name: BTL-899M
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: November 27, 2023
Received: November 27, 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,

Heather L. Dean -S

for CDR Jitendra Virani, MS, MBA
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)*
K232937

Device Name
BTL-899M

Indications for Use *(Describe)*
The BTL-899M device is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.
The BTL-899M device is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes.

Indications for Use for Muscle Stimulators:
- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

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

K232937

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:	21 December 2023

Device Name

Trade/Proprietary Name:	BTL-899M
Regulation Number:	21 CFR 890.5850
Regulation Name:	Powered Muscle Stimulator
Regulatory Class:	Class II
Product Code:	IPF

Legally Marketed Predicate Device

The BTL-899M is a state-of-the-art device with accessories using the electromagnetic energy for therapeutic purposes 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:

- HPM-6000 (K160992)

Product Description

The BTL-899M is a non-invasive therapeutic device. The device is comprised of a main unit and an applicator that deliver electromagnetic energy to the targeted tissue. The device's output enables hands-free treatment.

The application of electromagnetic energy to the patient should result in patient's feeling of magnetic stimulation of underlying muscles, joints and connective tissue accompanied by a pleasant feeling of warming sensation in the application area, which may contribute to increased local blood circulation and help the patient to relax and make the treatment more comfortable.

The BTL-899M 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 displays information about the applied therapy type, remaining therapy time and main therapy parameters on the screen.

Indications for Use

The BTL-899M device is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

The BTL-899M device is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes.

Indications for Use for Muscle Stimulators:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

Non-clinical Testing (Performance, Bench Testing)

The BTL-899M 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 compatibility – 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

Clinical Testing

Not applicable

Technological Characteristics

The BTL-899M device has the same intended use and identical technological characteristics and principles of operation to its predicate device. The BTL-899M device and its predicate are comprised of a system console and an applicator. The system console consists of the generators, computer, and the touch-screen control panel.

The mechanism of action and technological similarities and differences between the BTL-899M 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**	**K232937** BTL-899M BTL Industries, Inc.	**K160992** HPM-6000 BTL Industries, Inc.
Product Code and Regulation	Physical Medicine 21 CFR 890.5850 IPF – Stimulator, Muscle, Powered	Physical Medicine 21 CFR 890.5850 IPF – Stimulator, Muscle, Powered
Indications for Use	The BTL-899M device is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The BTL-899M device is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes. Indications for Use for Muscle Stimulators: • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle re-education • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Maintaining or increasing range of motion	The HPM-6000 device is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The HPM-6000 device is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes. Indications for Use for Muscle Stimulators: • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle re-education • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Maintaining or increasing range of motion
Electrical Protection	Class II, BF	Class II, BF
Interface	Touch screen	Touch-screen
Type of Energy	Electromagnetic energy for magnetic stimulation and application of warming sensation through radiofrequency	Magnetic field
Type of Applicator	Single magnetic coil	Single magnetic coil

Number of Magnetic coils in the Applicators	1	1
Number of Applicators	1	2
Color Touch Screen	15.6 in 39.6 cm 1920 x 1080 px.	8.4 in 21.3 cm 800×400 pixel
Type of Operation	Continuous	Continuous
Pulse Repetition Rate - supported by the device	1 – 150 Hz	1–150 Hz
Magnetic Field Intensity	AP-C-1 - 0.5 to 1.8 T	299-1 applicator: 0.5–1.8 T 299-2 applicator: 0.7–2.5 T
Pulse Duration	AP-C-1 - 280 µs ± 20%	299-1 applicator: 280 µs ± 20% 299-2 applicator: 280 µs ± 20%
Pulse Amplitude	0–100 %	0–100 %
Shape of Stimulation Pulse	Sine, biphasic	Sine, biphasic
RF Type	bipolar	N/A
Max. RF Power	30 W	N/A
RF Frequency	27.12 Mhz	N/A
Temperature Sensor	Yes	N/A
Therapy Time	Up to 30 min	Up to 60 min
Application	Hands-free, applicator fixed by fixation belt	Hands-free, applicator fixed in application arm
External Exchangeable Fuse	Yes	Yes
Energy Source	100 – 240 V AC, 50–60 Hz	100 – 240 V AC, 50–60 Hz
System Dimensions (W×H×D)	23 x 39 x 29 in (592 x 985 x 730 mm)	20×38×23 in (500 x 970 x 580 mm)
System Weight	70 kg	33 kg

Operating Ambient Temperature	+10°C to +30°C	+10°C to +30°C
Operating Relative Humidity	30% to 75%	30% to 75%
Environmental Specifications	For indoor use only In vertical position – On castors	For indoor use only In vertical position – On castors

Therapy Time

The subject device has a standard adjustable therapy duration of up to 30 minutes, which differs from the predicate device, which allows therapy to be set for up to 60 minutes. However, the device has the same output parameters as the predicate device in terms of maximum frequency, duty factor, maximum magnetic field intensity and pulse duration. If the operator deems it necessary to provide longer therapy to a patient, the subject device can be used repeatedly and the final dosage of energy delivered per the same time will be the same as for the predicate device. Therefore, this difference does not raise any unacceptable risks or unacceptable questions in relation to safety or efficacy.

Number of applicators

The applicator AP-C-1 is intended to be used with the subject device to achieve the intended purpose whereas the predicate device allows the use of one of two available applicators 299-1 or 299-2 to achieve the intended purpose of the device. The AP-C-1 applicator intended to be used with the subject device has the same maximum output parameters in terms of maximum magnetic field intensity and pulse duration as the predicate device applicator 299-1. Therefore, this difference does not raise any unacceptable risks or unacceptable questions in relation to safety or efficacy.

Weight & Dimensions

These parameters do not have any significant effect on the efficiency or safety of the device.

Additional energy and its parameters

BTL-899M incorporates application of the warming sensation on subtherapeutic level (up to 40°C) at the patient application site to increase patient convenience, soothe, and relax them during therapy. This application of additional energy does not raise any unacceptable risks or questions related to safety or effectiveness.

Temperature sensor

BTL-899M incorporates application of the warming sensation on subtherapeutic level (up to 40°C) at the patient application site to increase patient convenience, soothe and relax them during therapy. Based on this additional energy presence, there is a temperature sensor to monitor and regulate this additional modality. This application of additional energy does not raise any unacceptable risks or questions related to safety or effectiveness.

Substantial Equivalence

The BTL-899M device has the same intended use as its predicate device. The technological characteristics of the predicate device are similar to the BTL-899M device. Any differences between the predicate device and BTL-899M have no significant influence on safety and effectiveness of the BTL-899M device. Therefore, the BTL-899M is substantially equivalent to the predicate device.

Conclusion

Based upon the intended use and the known technical and clinical data provided in this pre-market notification, the BTL-899M device has been shown to be substantially equivalent to the currently marketed predicate device.