August 17, 2024

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

Re: K240234
Trade/Device Name: Btl-899ms
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, NGX
Dated: July 9, 2024
Received: July 9, 2024

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,

Jitendra V. Virani -S

CDR Jitendra Virani
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240234

Device Name

BTL-899MS

Indications for Use *(Describe)*

BTL-899MS 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.

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

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:	14 August 2024

Device Name

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

Legally Marketed Predicate Device

The BTL-899MS is a state-of-the-art device with accessories using the electromagnetic energy for therapeutic purposes and is substantially equivalent to the current products that are already cleared for distribution in the USA under the following 510(k) Premarket Notification numbers:

Primary predicate:

Device name: emField
Original 510(k) Sponsor: Zimmer MedizinSysteme GmbH
510(k) Number: K203488

Second predicate:

Device name: BTL-703-2
Original 510(k) Sponsor: BTL Industries, Inc
510(k) Number: K200382

Third predicate:

Device name: MAGNETOLITH
Original 510(k) Sponsor: Storz Medical AG
510(k) Number: K203710

Product Description

The BTL-899MS is a non-invasive therapeutic device. The device is comprised of a main unit and applicators that deliver electromagnetic energy to the targeted tissue. The device's two outputs enable hands-free simultaneous treatment by two applicators.

The application of electromagnetic energy to the patient should result in patient's feeling of magnetic stimulation of underlying tissue accompanied by a pleasant feeling of warming 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-899MS is equipped with a large color touch-screen that 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 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

BTL-899MS 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.

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

The BTL-899MS 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-899MS 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-899MS device has the same intended use and identical technological characteristics and principles of operation to its predicate devices. The BTL-899MS device and its predicates are comprised of a system console and applicator(s). 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-899MS device and the predicate devices are described below in the comparison table. The differences do not raise any new types of safety or effectiveness questions.

Substantial Equivalence

The subject device is capable of providing therapy in two output channels. The device is able to start the therapy and carry out the same treatment in both channels at the same time, with parameters (pulse duration, magnetic field intensity, and frequency) adjustable for each channel separately within the ranges described in the table below. This allows each channel to function as a full-function output. The device is still intended to be used on only one patient at a time, and the two channels are not intended to be used on the same muscle or on agonist and antagonist muscles. The ability to adjust the parameters and output power (intensity) separately for each channel allows the output power of each applicator to be tailored to the needs of the patient and the area being treated. This approach allows optimization of the treatment and ensures that each treated area receives the necessary stimulation. Therefore, this functionality does not raise any unacceptable risks or any unacceptable safety or effectiveness questions compared to the predicate device.

The magnetic field intensities, pulse durations, and magnetic energy densities of the subject device are within the range of values of the primary predicate (K203488) and third predicate (K203710) devices, which are both cleared for the same indications as the subject device under product code IPF. Therefore, these differences do not raise any unacceptable risks or any unacceptable safety or effectiveness questions compared to the predicate devices. The magnetic field intensities, pulse durations, and magnetic energy densities of the subject device are equivalent to the range of values of the second predicate device (K200382) that is cleared for the same indications as the subject device under product code NGX.

The maximum energy density delivered by the primary predicate device could be greater than the maximum energy density delivered to the tissue by the subject device, but energy densities delivered by the applicators of the subject device are within the set range of energy densities of the primary and third predicate devices. If we follow the instructions for the use of these devices, the device settings and maximum therapy intensity should be adjusted based on patient feedback and after careful consideration of the patient's adequate needs by the physician. As for the lower total value of energy

delivered to the tissue by the subject device compared to primary predicate, this total value of energy delivered, if deemed appropriate by the physician, can be adjusted to be equivalent to the primary predicate device by extending the time of application of the therapy. Therefore, these differences do not raise any unacceptable risks or any unacceptable safety or effectiveness questions compared to the predicate devices.

The subject device has a standard adjustable therapy duration of up to 30 minutes, which differs from the primary predicate device, which allows therapy to be set for up to 60 minutes and from the third predicate device, which allows therapy to be set for up to 20 minutes. However, the device has comparable output parameters to the primary predicate device in terms of maximum frequency, maximum magnetic field intensity and pulse duration. The subject device also fits within the set range of these parameters by its predicate devices. 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 comparable as for the predicate device. Therefore, this difference does not raise any unacceptable risks or unacceptable questions in relation to safety or efficacy.

BTL-899MS incorporates application of the warming on sub-therapeutic level at the patient application site to increase patient convenience during therapy. Based on this additional energy presence, there is a temperature sensor to monitor and regulate this additional modality. The application of additional warming as a supportive modality to increase comfort and provide a more convenient therapy has been used and already cleared for the second predicate device. Therefore the application of additional energy does not raise any unacceptable risks or questions related to safety or effectiveness.

The differences related to weight & dimensions, color touch screen size and storage conditions parameters do not have any significant effect on the efficiency or safety of the device.

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

Conclusion

Based upon the comparison of the intended use and the technological characteristics, the BTL-899MS device has been shown to be substantially equivalent to the currently marketed predicate devices.

Comparison with the Predicate Device

510(k) number **Device name** **Company name**	**Not assigned** BTL-899MS BTL Industries, Inc.	**K203488** emField Zimmer MedizinSysteme GmbH	**K200382** BTL-703-2 BTL Industries, Inc.	**K203710** MAGNETOLITH Storz Medical AG
	Subject device	Primary predicate	Second predicate	Third predicate
Product Code and Regulation	Physical Medicine 21 CFR 890.5850 IPF – Stimulator, Muscle, Powered NGX – Stimulator, Muscle, Powered, Muscle Conditioning	Physical Medicine 21 CFR 890.5850 IPF – Stimulator, Muscle, Powered	Physical Medicine 21 CFR 890.5850 NGX – Stimulator, Muscle, Powered, Muscle Conditioning	Physical Medicine 21 CFR 890.5850 IPF – Stimulator, Muscle, Powered NGX – Stimulator, Muscle, Powered, Muscle Conditioning
Indications for Use	The BTL-899MS device 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. The BTL-899MS device is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The BTL-899MS device is indicated for use in stimulating	The emField is indicated to be used for: • Relaxation of muscle spasms; • Prevention or retardation of disuse atrophy; • Increasing local blood circulation; • Muscle reeducation; • Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis; and • Maintaining or increasing range of motion.	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.	Indications for Use: • 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

	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 I, BF	Class II, BF	Class I, B
Clinical Use	Prescription use	Prescription use	Prescription use	Prescription use
Interface	Touch screen	Touch screen	Touch screen	Touch screen
Type of Energy	Electromagnetic stimulation accompanied by bipolar radiofrequency	Magnetic field	Electromagnetic stimulation accompanied by bipolar radiofrequency	Magnetic field
Number of Magnetic coils in the Applicators	1	1	1	1
Number of Applicators	2	2	2	1
Number of output channels	2	1	2	1

Color Touch Screen	15.6 in 39.6 cm 1920 x 1080 px.	7”	15.6 in 39.6 cm 1920 x 1080 px.	4-line, 7-segment display for viewing and setting therapy parameters
Type of operation	Continuous	Continuous	Continuous	Continuous
Pulse Repetition Rate - supported by the device	1 – 150 Hz	1 – 150 Hz	1 – 150 Hz	1-10Hz
Magnetic Field Intensity	AP-C-1 - 0.5 to 1.8 T +/-20% AP-C-2 - 0.7 to 2.0 T +/-20%	Large applicator: 0.5 – 1.5 T +/-20% Small applicator: 0.5 – 2.0 T +/-20%	AP-C-1 - 0.5 to 1.8 T +/-20% AP-C-2 - 0.7 to 2.0 T +/-20%	0.4T ±20% at surface 0.08T ±20% at center of coil
Pulse Duration	AP-C-1 - 280 µs ± 20% AP-C-2 - 190 µs ± 20%	Large applicator: 400 µs +/- 20% Small applicator: 250 µs +/- 20%	AP-C-1 - 280 µs ± 20% AP-C-2 - 190 µs ± 20%	125µs ± 20%
Pulse Amplitude	0–100 %	0–100 %	0–100 %	multiple adjustable intensity levels
Stimulation Pulse	Sine, biphasic	Sine, biphasic	Sine, biphasic	Damped sinus, biphasic
Magnetic energy density - Range of the device (J/m3)	AP-C-1 – 21.93 – 284.26 AP-C-2 – 19.8 – 161.59	Large applicator: 44.76 – 402.9 Small applicator: 17.49 – 279.76	AP-C-1 – 21.93 – 284.26 AP-C-2 – 19.8 – 161.59	0.002 – 0.050
RF Type	bipolar	N/A	bipolar	N/A
Max. RF Power	30W per applicator	N/A	30W per applicator	N/A
RF Frequency	27.12 Mhz	N/A	27.12 Mhz	N/A

Temperature Sensor	Yes	N/A	Yes	N/A
Therapy Time	Up to 30 min	Up to 60 min	Up to 30 min	Up to 20 min
Energy Source	100 – 240 V AC, 50–60 Hz	100 – 240 V AC, 50–60 Hz, max. 12,5 A	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)	542 x 501 x 993 mm	23 x 39 x 29 in (592 x 985 x 730 mm)	454 x 187 x 460 mm
System Weight	70 kg	60 kg	85 kg	Not known
Ambient Storage Temperature	-10°C to +55°C	Not known	-10°C to +55°C	10 – 20°C
Relative Storage Humidity	10% to 85%	Not known	10% to 85%	5 – 55%
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	For indoor use only