August 7, 2025

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

Re: K250309
Trade/Device Name: BTL-199
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: QPL
Dated: January 28, 2025
Received: February 3, 2025

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,

Amber T. Ballard -S

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
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Physical Medicine Devices
Office of Product Evaluation and Quality
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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.

510(k) Number *(if known)*
K250309

Device Name
BTL-199

Indications for Use *(Describe)*
The BTL-199 is intended to stimulate peripheral nerves for relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities. The BTL-199 is for use on patients 18 and older.

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
K250309

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:	6 August 2025

Device Name

Trade/Proprietary Name:	BTL-199
Primary Classification Name:	Electromagnetic Stimulator, Pain Relief
Classification Regulation:	882.5890, Class II
Classification Product Code:	QPL

Legally Marketed Predicate Device

The BTL-199 is a state-of-the-art electromagnetic energy device with accessories and is substantially equivalent to the current product that is already cleared for distribution in the USA under the following 510(k) Premarket Notification numbers:

Predicate device #1:
Device name: Axon Therapy
Original 510(k) Sponsor: NeuraLace Medical Inc.
510(k) Number: K233364

Predicate device #2:
Device name: MagVenture Pain Therapy
Original 510(k) Sponsor: Tonica Elektronik A/S
510(k) Number: K230014

Product Description

The BTL-199 is an electromagnetic stimulator that delivers brief, focused electromagnetic pulses to non-invasively stimulate peripheral nerves, providing pain relief.

The device consists of a main unit and specialized applicators, designed to deliver precise and effective therapy. The main unit is equipped with an intuitive color touch screen that provides step-by-step guidance for the operator throughout the therapy process. The device features a preset treatment protocol for ease of use, while also allowing operators to customize parameters to meet specific therapeutic needs. Adjustable parameters include frequency (up to 150 Hz), therapy time (up to 30 minutes), and intensity (0-100%). The interface displays detailed information about the therapy settings and session progress (i.e., treatment duration).The device uses a temperature sensor to monitor the temperature of the coil to ensure that the maximum permissible temperature of the applicator's contact areas (i.e., 43°C) are not exceeded. It also has an intensity predictor function that limits the maximum adjustable intensity of the device based on the therapy parameters set, so as not to overheat and damage the device.

The device is equipped with three sets of applicators: AP-C-1, AP-C-2, and AP-C-4/5. Each applicator is intended for a different body area depending on the size and shape of the treated body part.

- Applicator AP-C-1 is intended for treatment of larger body areas, such as back, waist, thighs, etc.
- Applicator AP-C-2 is intended for treatment of smaller body areas, such as hands, arms, legs, etc.
- Applicators AP-C-4/5 (AP-C-4 and AP-C-5 - for each side of the body respectively) is primarily intended for treatment of waist and lower back.

Indications for Use

The BTL-199 is intended to stimulate peripheral nerves for relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities. The BTL-199 is for use on patients 18 and older.

Non-clinical Testing (Performance, Bench Testing)

The BTL-199 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 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

Temperature testing at the applicator surface was also provided to ensure it remained within safe non-therapeutic levels, in addition to validation testing for the temperature sensor and intensity predicator function.

Clinical Testing

Not applicable

Technological Characteristics

The BTL-199 device has the same intended use and comparable technological characteristics and principles of operation to its predicate devices. The BTL-199 device and its predicates are comprised of a system console and applicator(s). The system console consists of the generators, computer, and the control panel.

The mechanism of action and technological similarities and differences between the BTL-199 device and the predicate devices are described below in the comparison table. The differences do not raise any new safety or effectiveness questions.

Substantial Equivalence

The subject device has the same intended use and comparable technological characteristics and principles of operation to its predicate devices. Therefore, the subject device is substantially equivalent to the predicate device.

Comparison with the Predicate Devices

510(k) number **Device name** **Company name**	**K250309** **BTL-199** **BTL Industries, Inc.**	**K233364** **Axon Therapy** **NeuraLace Medical Inc.**	**K230014** **MagVenture Pain Therapy** **Tonica Elektronik A/S**	
	Subject device	**Predicate device**	**Predicate device**	
Regulation	21 CFR 882.5890 Transcutaneous electrical nerve stimulator for pain relief.	21 CFR 882.5890 Transcutaneous electrical nerve stimulator for pain relief.	21 CFR 882.5890 Transcutaneous electrical nerve stimulator for pain relief.	None
Product code(s)	QPL	QPL IPF	QPL	None
Indications for use	The BTL-199 is intended to stimulate peripheral nerves for relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities. The BTL-199 is for use on patients 18 and older.	The Axon Therapy is intended to stimulate peripheral nerves for relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities. The Axon Therapy is for use on patients 18 and older.	The MagVenture Pain Therapy is intended to stimulate peripheral nerves for relief of chronic intractable, post traumatic and post-surgical pain for patients 18 years or older.	None
Therapy protocol	Therapy intensity: Individually estimated Therapy time: 800 s Therapy frequency: 0.5 Hz Number of pulses: 400	Therapy intensity: Individually estimated Therapy time: 800 s Therapy frequency: 0.5 Hz Number of pulses: 400	Therapy intensity: Individually estimated Therapy time: 800 s Therapy frequency: 0.5 Hz Number of pulses: 400	None

Treatment areas	Any area, such as hand, arm, waist, buttock, thigh, calf, back and lower back etc.	Any area,such as hand, arm, chest, waist, buttock, thigh, calf, back and low back etc.	Any area,such as hand, arm, waist, buttock, thigh, calf, back and lower back etc.	None
Treatment facilities	Hospitals & Clinics	Hospitals & Clinics	Hospitals & Clinics	None
Basic technology	Electromagnetic stimulation	Electromagnetic stimulation	Electromagnetic stimulation	None
Pulse frequency	0.5 Hz per protocol Up to 150 Hz ● AP-C-1 (150 Hz) ● AP-C-2 (50 Hz) ● AP-C-4/5 (150 Hz)	0.5 Hz per protocol Up to 2 Hz	0.5 Hz per protocol Up to 100 Hz	Not significantly different
Maximum repetition rate	Up to 150 pps ● AP-C-1 (150 pps) ● AP-C-2 (50 pps) ● AP-C-4/5 (150 pps)	Up to 2 pps	Up to 100 pps	Not significantly different compared to K230014 predicate device.
Pulse amplitude	0-100%	0 to 100% A maximum of 80% intensity is recommended to reduce the risk of coil overheating	0-100%	None
Therapy time	13 min per protocol (800 seconds) Up to 30 minutes	13 min per protocol (800 seconds)	13 min per protocol (800 seconds)	Not significantly different
On-Cycle Duty Period	800 s per protocol	800 s per protocol	800 s per protocol	None

	Device Therapy/On time period is up to 30 minutes	Device Therapy/On time period is up to 800 seconds	Device Therapy/On time period is up to 800 seconds	
Off-duty rest period	N/A	N/A	N/A	None
Pulse mode	Standard	Standard	Standard	None
Pulse width (±20 %)	Biphasic (190-280 µsec) • AP-C-1 (280 µsec) • AP-C-2 (190 µsec) • AP-C-4/5 (260 µsec)	Biphasic (290 µsec)	Biphasic (280-320 µsec)	Not significantly different
Maximum output power	100% at up to 14 pps • AP-C-1 (13 Hz) • AP-C-2 (14 Hz) • AP-C-4/5 (8 Hz)	100% at 2 pps	100% at up to 15 pps	Not significantly different compared to K230014 predicate device
Waveform	Biphasic	Biphasic	Biphasic, Halfsine, Biphasic Burst, Monophasic	None
Maximum surface temperature	Below 43°C (on applicator surface)	45°C or 41°C for total of 9 minutes (on coil surface)	43°C (or 48ºC for <10 minutes)	None
Peak Magnetic Field at coil surface (T)	Up to 2.0 T • AP-C-1 (0.5 to 1.8 T) • AP-C-2 (0.7 to 2.0 T) • AP-C-4/5 (0.35 to 1.3 T)	Not publicly available	Up to 2.6 T	Not significantly different

Peak Magnetic Field Gradient dB/dt in coil center at 20mm distance from the applicator surface	Up to 16 kT/s • AP-C-1 (10 kT/s) • AP-C-2 (16 kT/s) • AP-C-4/5 (11 kT/s)	Not publicly available	Up to 26 kT/s	Not significantly different
Applied parts and applied parts areas	AP-C-1 (14.6 cm) AP-C-2 (13.6 cm) AP-C-4/5 (29.3 cm)	Coil 60BF-NL 16 cm	Butterfly coils: 150 mm Circular coils:110-126 mm Special coils: 160×80 mm (MMC-140-II, MCF-140, RT-120-II, MMC-90, MCF-125, Cool-B65, Cool-125)	None Both devices were tested in accordance with ISO 10993 series
Timer	Yes	Not publicly available	Not publicly available	Not significantly different
Software/ Firmware/ Microprocessor control	Yes	Yes	Yes	None
Indication Functions	On/Off Status Ready Status	On/off status Ready status	Not publicly available	None
Power source	100 – 240 V AC, 50–60 Hz	100 – 240 V AC, 50–60 Hz	120V AC, 50/60 Hz	None
Power consumption	3000 W	Power consumption: 800VA Maximum, 115W idle	Maximum 2700VA	Not significantly different
User Interface	Touch screen	LED display	LED display	Not significantly different

Housing Material Construction	Main unit – Aluminium alloy, ABS, PC, Stainless steel Applicator - PC-ABS, PE	Stimulator: AL sheet EN AW 5754 H111 Coil: ABS	Stimulator: Aluminum, Aluzinc Coils: PVC, ABS, PA, POM	Not significantly different
Coil construction and parameters	Single copper coil with air core.	Butterfly copper coil with air core.	Butterfly, Single or Special coils with copper winding and air core.	Not significantly different
Weight & Dimensions	Stimulator: 70 kg Including packaging and accessories: 91 kg Applicators: AP-C-1 – 2.7 kg AP-C-2 – 2.3 kg AP-C-4/5 – 2 kg Unit with cart: 23 x 39 x 29 in (592 x 985 x 730 mm)	Stimulator: 17 kg Coil: 3.2 kg Full system (with cart): 54 kg Unit: 485 x 380 x 165 mm	Not publicly available Stimulator: 210 × 530 × 400 mm 33 kg/35 kg	Not significantly different
Sterilization	Non-sterile when used	Non-sterile when used	Non-sterile when used	None

Substantial Equivalence Discussion

Therapy Time

The therapeutic protocol cleared for the predicate device specifies a treatment time of 13 minutes; however, each patient is unique and requires an individualized approach. Since this device is intended for use by medical professionals as an Rx-only device, it allows therapy durations of up to 30 minutes. We believe that treatment length should be determined by the physician based on each patient's condition, and therefore offer this option. Additionally, the default time settings for the cleared therapy protocol are the same as those for the predicate device: 800 seconds.

In case of use therapy parameters that would be outside the recommended parameters stated above, the device has several built-in functions which should help to avoid any undesirable effects - e.g. a therapy discomfort button, which must be available to the patient at all times during therapy and which can be used to interrupt the therapy in case of any discomfort (its use should prevent any overstimulation, pain or any discomfort sensation or thermal damage to the patient). There is also a temperature sensor that constantly monitors the temperature of the coil to ensure that the maximum permissible temperature of the applicator's contact areas are not exceeded (its use should prevent thermal damages to the patient). The device also has an intensity predictor function that limits the maximum adjustable intensity of the device based on the therapy parameters set, so as not to overheat and damage the device. The Operator's manual also urges the operator to regularly monitor the patient's feedback and never leave the patient alone during therapy.

For the reasons outlined above, this difference does not introduce any new or modified risks or concerns related to safety or effectiveness and the subject device is equivalent to the selected predicate.

Maximum Repetition Rate / Pulse Frequency

The subject device's maximum pulse repetition rate of 150 pps exceeds the predicate device's 2 pps; however, subject device's maximum pulse repetition rate is very similar to K230014. Moreover, the subject device is intended for prescription use only (Rx-only), meaning it must always be prescribed by a physician, who is responsible for the final settings of therapy parameters for each individual patient and as mentioned above, the subject device allows physicians to set the same preset protocol as its predicate.

From the effectiveness and design point of view, the subject device is comparable to the K233364 predicate device - since the subject device allows the use of a therapeutic protocol with the same parameters that were cleared for the K233364 predicate device and these therapeutic parameters for achieving the indications for use are also described in the operator's manual.

- Therapy intensity: Individually estimated
- Therapy time: 800 s
- Therapy frequency: 0.5 Hz
- Number of pulses: 400

The operator's manual clearly states that treatment parameters (e.g., repetition rate, pulses per train, number of trains, number of pulses, inter train interval, treatment time)

not included in the list above have not been evaluated for effectiveness in the relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities.

For the reasons outlined above, the subject device is comparable to predicate devices, and this difference does not introduce any new or modified risks or concerns related to safety or effectiveness.

Maximum Output Power

The subject device's maximum output power is very similar to K230014.The maximum output power of the subject device is 100% at frequencies up to 14 Hz, compared to the K233364 predicate device, which maintains 100% output up to 2 Hz. However, at the therapeutic protocol frequency of 0.5 Hz, both devices are capable of maintaining a maximum output of 100% intensity throughout the entire 800 s therapy duration. At 2 pps the subject device and the K233364 device are both able to obtain a maximum output of 100% signifying they are equally effective. This demonstrates that both devices are comparably effective. The difference in maximum output power does not raise new or different questions of safety and effectiveness.

Magnetic Coil Construction

The subject device applicators use a single, circular-coil design, whereas the K233364 predicate device employs a figure-of-eight (double) coil. The K230014 predicate uses both circular and butterfly coils. Both coil types are similarly constructed - copper windings encapsulated in a plastic housing, and operate on the same basic principle: a time-varying magnetic field induces an electric field in tissue that depolarizes nerve axons. Circular coils offer the practical advantage of unrestricted orientation, however, both geometries achieve the same intended peripheral-nerve-stimulation effect.

The differences in spatial distribution of the magnetic field, and its parameters such as maximum surface flux density (T) or field gradient (dB/dt) between circular and double coils are negligible in practice and have not been shown to affect safety or efficacy. Therefore, this difference does not introduce any new or modified risks or concerns related to safety or effectiveness.

Conclusion

Based upon the intended use and the known technical data provided in this pre-market notification, the BTL-199 device has been shown to be substantially equivalent to the currently marketed predicate devices.