June 12, 2026

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

Re: K252963
Trade/Device Name: BTL-899TT
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave Diathermy
Regulatory Class: Class II
Product Code: IMJ
Dated: September 15, 2025
Received: September 17, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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.

510(k) Number *(if known)*
K252963

Device Name

BTL-899TT

Indications for Use *(Describe)*
BTL-899TT is indicated to be used in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as disorders of the musculoskeletal system, muscle spasm, joint stiffness, contractures, and chronic inflammatory or infective conditions such as tenosynovitis, bursitis, synovitis and chronic inflammatory pelvic diseases.

Generally accepted indications for use:

- o Pain Relief
- o Contractures
- o Reduce Muscle Spasm
- o Localized increase Blood Flow
- o Chronic Inflammatory Conditions
- o Bursitis
- o Decrease Joint Stiffness
- o Tenosynovitis
- o Synovitis
- o Chronic Inflammatory Pelvic Disease

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.

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510(k) Summary
K252963

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:	10 June 2026

Device Name

Trade/Proprietary Name:	BTL-899TT
Common Name:	Diathermy, Shortwave, For Use In Applying Therapeutic Deep Heat
Regulation Number:	21 CFR 890.5290
Classification Name:	Shortwave diathermy
Regulatory Class:	Class II
Product Code:	IMJ

Legally Marketed Predicate Device

The BTL-899TT uses radiofrequency energy for the therapeutic application of deep heat 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:

Predicate device:

Device name: ThermoPro
Original 510(k) Sponsor: Zimmer MedizinSysteme GmbH
510(k) Number: K161862

Device Description

The BTL-899TT is a non-invasive therapeutic device consisting of a main unit and applicators (899-AP-C-1, 899-AP-C-2, 899-AP-C-4 and 899-AP-C-5) designed to deliver electromagnetic energy of 27.12 MHz to targeted tissues. The device is intended for use in applying therapeutic deep heat to body tissues for the treatment of selected medical conditions such as disorders of the musculoskeletal system, muscle spasm, joint stiffness, contractures, and chronic inflammatory or infective conditions such as tenosynovitis, bursitis, synovitis and chronic inflammatory pelvic diseases. The device enables hands-free operation. When therapy is applied, the patient should experience a pleasant warming sensation in the treatment area. The device is intended solely for professional use in healthcare facilities. The device is designed for indoor use only. The device is not intended for home-use.

The BTL-899TT 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-899TT is indicated to be used in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as disorders of the musculoskeletal system, muscle spasm, joint stiffness, contractures, and chronic inflammatory or infective conditions such as tenosynovitis, bursitis, synovitis and chronic inflammatory pelvic diseases.

Generally accepted indications for use:

- o Pain Relief
- o Contractures
- o Reduce Muscle Spasm
- o Localized increase Blood Flow
- o Chronic Inflammatory Conditions
- o Bursitis
- o Decrease Joint Stiffness
- o Tenosynovitis

o Synovitis
o Chronic Inflammatory Pelvic Disease

Non-clinical Testing (Performance, Bench Testing)

The BTL-899TT device has been thoroughly evaluated for electrical safety, biocompatibility, electromagnetic compatibility, software, and performance. 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

Thermal characterization testing to demonstrate that the device can maintain temperature in the range of approx. 40-43°C using a tissue-mimicking material was conducted. The results of this evaluation confirmed the ability of the BTL-899TT device to maintain therapeutic heating levels for the duration of therapy and that the surface temperature sensor ensures that the body surface temperature does not exceed 43°C (±1°C).

Clinical Testing

Not applicable

Technological Characteristics

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

The technological similarities and differences between the BTL-899TT device and the predicate device are presented below in the comparison table. The differences do not raise any increased safety or effectiveness concerns compared to the predicate device.

Comparison with the Predicate Device

510(k) number Device name Company name	K252963 BTL-899TT BTL Industries, Inc.	K161862 ThermoPro Zimmer MedizinSysteme GmbH	Similarities/ Difference
	Subject device	Predicate device	
Product Code and Regulation	Physical Medicine 21 CFR 890.5290 IMJ – Diathermy, Shortwave, for use in applying therapeutic deep heat	Physical Medicine 21 CFR 890.5290 IMJ – Diathermy, Shortwave, for use in applying therapeutic deep heat	**Same**
Indications for Use	BTL-899TT is indicated to be used in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as disorders of the musculoskeletal system, muscle spasm, joint stiffness, contractures, and chronic inflammatory or infective conditions such as tenosynovitis, bursitis, synovitis and chronic inflammatory pelvic diseases. Generally accepted indications for use: o Pain Relief o Contractures o Reduce Muscle Spasm o Localized increase Blood Flow o Chronic Inflammatory Conditions o Bursitis o Decrease Joint Stiffness o Tenosynovitis o Synovitis o Chronic Inflammatory Pelvic Disease	Indications for use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as disorders of the musculoskeletal system, muscle spasm, joint stiffness, contractures, and chronic inflammatory or infective conditions such as tenosynovitis, bursitis, synovitis and chronic inflammatory pelvic diseases. Generally accepted indications for use: • Pain Relief • Contractures • Reduce Muscle Spasm • Localized increase Blood Flow • Chronic Inflammatory Conditions • Bursitis • Decrease Joint Stiffness • Tenosynovitis • Synovitis • Chronic Inflammatory Pelvic Disease.	**Same**
Electrical Protection	Class II, BF	Class I, BF	**Same**
Clinical Use	Prescription use	Prescription use	**Same**

Interface	Touch screen	Touch screen	**Same**
Type of Energy	Deep heating of tissue by therapeutic application of radio frequency electrical currents	Deep heating of tissue by therapeutic application of radio frequency electrical currents	**Same**
Color Touch Screen	15.6 in 1920 x 1080 px.	Not publicly available	The difference in display size and resolution represents a modification to the user interface and has no direct impact on the therapeutic effect of the device.
Type of operation	Continuous	Continuous and Pulsed	Both devices heat the target tissue to a therapeutic temperature range; from a safety perspective, the device is capable of regulating its output to prevent the target tissue from overheating beyond the required temperature range, as confirmed by performance bench testing. This difference does not raise increased concerns regarding safety or efficacy.
Output intensity	0–100 %	Not publicly available	The representation of output intensity in relative values (0–100%) is a standard approach to user power settings and is one of the possible ways to indicate a device's output intensity. This difference does not impact safety or efficacy.
RF Type	Capacitive	Not publicly available	The subject device utilizes a capacitive type of radiofrequency energy transfer, which is one of the established methods for shortwave diathermy to heat tissue. The lower maximum power of the subject device does not affect its ability to reach the therapeutic temperature range, as verified through performance bench testing.
Max. RF Power @50Ohm	30W per applicator (2x)	Output Power: 100W Pulsed Output Power: 200W	
RF Frequency	27.12 Mhz	27.12 Mhz	**Same**
Temperature Sensor	Yes	Not publicly available	The subject device is equipped with a temperature sensor that monitors the temperature on the patient's body surface at the application site. The functionality of the sensor was verified through software validation

			and the provided performance bench testing. This difference does not raise increased safety concerns compared to the predicate device.
Therapy Time **Displayed**	Up to 30 min Yes	Up to 30 min Yes	**Same**
Favorites programs	Yes	Yes	**Same**
Energy Source	100 – 240 V AC, 50–60 Hz	100 – 240 V AC, 50–60 Hz,	**Same**
System Dimensions (W×H×D)	23 x 39 x 29 in (592 x 985 x 730 mm)	33.64 h x 22.9 w x 18.0 d in (854 x 581 x 459 mm)	The differences in physical dimensions and weight between the subject device and the predicate device are due to the distinct designs of the two devices and have no impact on device safety or efficacy.
System Weight	70 kg	37 kg	
Ambient Storage Temperature	-10°C to +55°C	Not publicly available	**Similar**
Relative Storage Humidity	10% to 85%	Not publicly available	**Similar**
Environmental Specifications	For indoor use only	Not publicly available	**Similar**

Substantial Equivalence Discussion

The technological differences between the subject device and the predicate device identified in the SE table below include the RF type, maximum output power, and physical parameters (weight, dimensions, and display size).

Although the devices differ in the used RF Type specifically, both devices operate at an identical frequency of 27.12 MHz. They both produce the same heating effect in the treated tissue, whether through dielectric losses or eddy currents, and result in comparable temperature rises to achieve therapeutic deep heating.

The difference in maximum output power does not affect the ability of the subject device to achieve the required thermal effect in the treated tissue, as the subject device, like the predicate device, is capable of reaching and maintaining the therapeutic deep heating range.

Therefore, these differences do not introduce any new or modified risks or concerns related to safety or effectiveness, and the subject device, BTL-899TT, has been shown to be substantially equivalent to the cleared predicate device.

Conclusion

Based upon the intended use and the technical data provided in this pre-market notification, the BTL-899TT device is substantially equivalent to the K161682 predicate device.