January 24, 2019

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

Re: K182363
Trade/Device Name: BTL-703
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave Diathermy
Regulatory Class: Class II
Product Code: IMJ
Dated: December 20, 2018
Received: December 26, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182363

Device Name
BTL-703

Indications for Use *(Describe)*
BTL-703 is indicated to be used for applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as: 1. Relieving pain; 2. Reducing muscle spasm; 3. Increasing range of motion of contracted joints using heat and stretch techniques; and 4. Increasing blood flow to tissues in the treatment area.

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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"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."

BTL Industries

K182363

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:	January 21, 2019

Device Names

Trade/Proprietary Name:	BTL-703
Primary Classification Name:	Diathermy, Shortwave, For Use In Applying Therapeutic Deep Heat
Classification Regulation:	890.5290
Product Code:	IMJ

Predicate Device

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

- K120093, BTL Elite

Product Description

The BTL-703 is comprised of a device unit and applicator that deliver radiofrequency energy to the targeted tissue. The device is designed to enable hands-free treatment. Easy-to-use color touch screen allows for maximum operator comfort. The main unit is placed in a specially designed cart, the shape of which provides maximum operator comfort and easy movement of the device in the office.

The BTL-703 consists of the following main components:

- microprocessor-driven control unit
- high-frequency energy generator
- user interface with 15,6" HD touch screen
- four-point applicator

Indications for Use

BTL-703 is indicated to be used for applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as: 1. Relieving pain; 2. Reducing muscle spasm; 3. Increasing range of motion of contracted joints using heat and stretch techniques; and 4. Increasing blood flow to tissues in the treatment area.

Non-clinical Testing

The BTL-703 device has been thoroughly evaluated for its safety and performance. The device has been found to comply with 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 Disturbance – 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

Animal Testing

In order to demonstrate the device is able to maintain temperature in the range of approx. 40-45°C in vivo, study in porcine model has been conducted. The results of this evaluation confirmed the ability of the BTL 703 device to maintain the temperature in the range of approx. 40-45°C in vivo.

Technological Characteristics

The BTL-703 device has similar technological characteristics compared to its predicate. Both devices comprised of a system console and applicator(s). The system console consists of the RF generator, computer, and the touch-screen control panel.

Both devices use high-frequency electromagnetic current for a purpose of deep heating of tissue. The BTL-703, compared to the predicate device, does not included pulsed mode of operation and inductive type of applicator. Output power of BTL-703 is divided into two outputs for more even energy distribution. Nevertheless, total maximum power output stays the same (200W) as by the predicted device. The working frequency is identical for both devices.

The BTL 703 is using negative pressure for applicator fixation compared to the predicate device using mechanical arm. Negative pressure under silicone applicator sleeves ensures uniform coupling between the capacitive electrodes and patient. The BTL-703 device also differs in the shape and dimensions when compared to its predicate. Nevertheless, these differences does not rise any new safety or effectiveness questions compared to the predicate.

Therefore, the BTL-703 has similar technological characteristics compared to its predicate device. A device comparison table comparing characteristics of the BTL-703 with the BTL Elite including the indications for use, is provided below.

510(k) number	**K182363**	**K120093**
Device name	BTL-703	BTL Elite
Company name	BTL Industries, Inc.	BTL Industries, Inc.
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

510(k) number **Device name** **Company name**	**K182363** BTL-703 BTL Industries, Inc.	**K120093** BTL Elite BTL Industries, Inc.
Indications for Use	BTL-703 is indicated to be used for applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as: 1. Relieving pain; 2. Reducing muscle spasm; 3. Increasing range of motion of contracted joints using heat and stretch techniques; and 4. Increasing blood flow to tissues in the treatment area.	Indications for Use: Indications for use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as: 1. Relieving pain; 2. Reducing muscle spasm; 3. Increasing range of motion of contracted joints using heat and stretch techniques; and 4. Increasing blood flow to tissues in the treatment area.
Principle of Action	Deep heating of tissue by therapeutic application of radio frequency electrical currents	Deep heating of tissue by therapeutic application of radio frequency electrical currents
Clinical Use	Prescription use	Prescription use
Electrical Protection	Class II, BF	Class I, BF
User Interface	Touch screen	Touch screen
Firmware Controlled	Yes	Yes
Type of Energy	High-frequency electromagnetic current	High-frequency electromagnetic current
Working frequency	27.12 MHz	27.12 MHz
Modes of operation	Continuous	Continuous Pulsed
Max Power Output	2 x 100 W (continuous)	200 W (continuous)

510(k) number **Device name** **Company name**	**K182363** BTL-703 BTL Industries, Inc.	**K120093** BTL Elite BTL Industries, Inc.
	N/A	400 W (pulsed)
Therapy Time	1 – 30 min	1 – 30 min
Applicators type	Capacitive	Capacitive
		Inductive
Capacitive Applicators Size	100 mm	42 mm
		85 mm
		130 mm
Inductive Applicators Size	N/A	80 mm
		140 mm
Way of Applicator Attachment	Negative pressure	Mechanical arm lock
Applicator Sleeves	Yes	No
Thermal Stabilization System	Yes	No
Arm control	Electrical / Mechanical	Mechanical
Hands-free Application	Yes	Yes
Stop Remote Control	Yes	Yes
Applicator Contact Monitor	Yes	Yes
System Dimensions (W×H×D)	627x985x674 mm (24.7x38.8x26.5 in)	560×980×560 mm (22.5×38.6×22.5 in)
Configuration	Cabinet-mounted with wheels	Cabinet-mounted with wheels

510(k) number	K182363	K120093
Device name	BTL-703	BTL Elite
Company name	BTL Industries, Inc.	BTL Industries, Inc.
Environmental Specifications	For indoor use only	For indoor use only

Substantial Equivalence

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

Conclusions

Performance data demonstrate that the differences between the BTL-703 and the predicate do not raise any new question regarding the safety or effectiveness.

Based on the aforementioned information, the BTL-703 is substantially equivalent to the identified predicate device.