April 14, 2023

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

Re: K221865
Trade/Device Name: BTL-094
Regulation Number: 21 CFR 890.5660
Regulation Name: Therapeutic Massager
Regulatory Class: Class I
Product Code: ISA
Dated: March 20, 2023
Received: March 20, 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 (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/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 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221865

Device Name
BTL-094

Indications for Use *(Describe)*
BTL-094 is indicated to be used for:

- Relief of minor muscle aches and pains.
- Temporary increase in local blood circulation.
- Activation of connective tissue.

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

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:	April 14, 2023

Device Name

Trade/Proprietary Name:	BTL-094
Primary Classification Name:	Therapeutic Massager
Common/Usual Name:	Therapeutic Massager
Classification Regulation:	21 CFR 890.5660, Class I
Classification Product Code:	ISA

Legally Marketed Predicate Device

The BTL-094 is a state-of-the-art device substantially equivalent to the following products, which are already cleared for distribution in the USA under the following 510(k) Premarket Notification number:

- **D-Actor 200 (K173692)**
- **DolorClast® Radial (K220538)**

Product Description

The BTL-094 is a non-invasive therapeutic device, which uses acoustic waves in order to stimulate a local biological response in the treated tissue.

The BTL-094 generates extracorporeally induced massage pulses to stimulate a local biological response in the treated tissue. The main source of acoustic waves is a piezo transducer inside the applicator. The energy transfer from the piezo transducer to the treated tissue is realized via coupling pad.

The main unit is equipped with a color touch screen, which considerably simplifies its operation. The on-screen information guides the user step-by-step through the entire therapy process. A secondary screen is placed on the applicator for the presentation of the actual state of main therapy parameters. The therapeutic parameters are adjustable via touch-screen, buttons and knob. The user is able to set following therapy parameters: intensity, frequency and number of shocks.

The mechanism of action and technological similarities and differences between the BTL-094 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.

Indications For Use

BTL-094 is indicated to be used for:

- Relief of minor muscle aches and pains.
- Temporary increase in local blood circulation.
- Activation of connective tissue.

Non-clinical Testing

The BTL-094 device has been thoroughly evaluated for electrical safety. The device has been found to comply with the following applicable medical device safety standards:

IEC 60601-1:2005/A1:2012 FR Recognition Number: 19-4	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014 FR Recognition Number: 19-8	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6:2010/A1:2013 FR Recognition Number: 5-89	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-36:2014 FR Recognition Number: 9-119	Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy
IEC 62304:2006/A1:2015 FR Recognition Number: 13-79	Medical device software – Software lifecycle processes
ISO 14971:2019 FR Recognition Number: 5-125	Medical devices – Application of risk management to medical devices
ISO 10993-1:2018 FR Recognition Number: 2-258	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009 FR Recognition Number: 2-245	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010 FR Recognition Number: 2-174	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

Clinical Testing

Not aplicable

Technological Characteristics

The BTL-094 is a non-invasive therapeutic device, which uses acoustic waves in order to stimulate a local biological response in the treated tissue.

The BTL-094 generates extracorporeally induced massage pulses to stimulate a local biological response in the treated tissue. The main source of acoustic waves is a piezo transducer inside the applicator. The energy transfer from the piezo transducer to the treated tissue is realized via coupling pad.

The mechanism of action and technological similarities and differences between the BTL-094 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.

Comparison with the Predicate Device

510(k) number **Device name** **Company name**	**K221865** **BTL-094** **BTL Industries Inc.**	**K173692** **D-Actor 200** **Storz Medical**	**K220538** **DolorClast® Radial** **EMS Electro Medical SA**	
Indications for Use	Relief of minor muscle aches and pains Temporary increase in local blood circulation Activation of connective tissue	*Relief of minor muscle aches and pains *Temporary increase in local blood circulation *Activation of connective tissue	- Relief of minor muscle aches and pains. - Temporary increase in local blood circulation. - Activation of connective tissue.	**None**
Product Code and Regulation	21 CFR 890.5660 ISA	21 CFR 890.5660 ISA	21 CFR 890.5660 ISA	**None**
Modes of Action	Extracorporeally induced pressure waves.	Radial pressure waves, or extracorporeal pulse activation respectively	Radial pressure waves, or extracorporeal pulse activation respectively	**Not Significantly different** Please see the discussion and conclusion below.
Mechanisms of Action	Vibrations generated by electroacoustic technology.	Pneumatically generated vibrations	Pneumatically generated vibrations	**Not Significantly different** Please see the discussion and conclusion below.
Maximum and Minimum intensity settings	5-30% alternative output power setting scale	1-5bar	1-4bar	**Not Significantly different** Differences are caused by alternative technology of the pressure wave generation.

Number and size of treatment applicator heads	2; L Pad - 12.2 cm^2 U Pad - 7.3 cm^2	4; 6mmOD, 15mmOD, 20mmOD, 35mmOD	7; 5mm OD, 10 mm OD, 15 mm OD, 25 mm OD, 40 mm OD	**Not Significantly different** The application area of the pads in contact with the patient is within the set range of the predicate devices. All materials in contact with the patient have been assessed for biocompatibility
Maximum and minimum displacements of applicator heads	N/A	0.6 – 2.0mm	0.18 - 0.28 mm	**N/A** The BTL-094 applicator does not have any moving parts that come in contact with the patient.
Type of application (e.g., continuous vibration at a fixed frequency);	Continuous vibration at a fixed frequency and single pulse mode	Continuous vibration at a fixed frequency	Continuous vibration at a fixed frequency	**None**
Maximum and minimum vibration frequency	1-25 Hz	1-21Hz	1-25 Hz	**Not Significantly different**
Power Supply	100 V to 240 V AC 50 - 60 Hz 150VA	500VA	Mains power	**None**
Maximum penetration depth	35 mm	32.3mm	40 mm	**Not Significantly different** Please see the discussion and conclusion below.
Energy flow density	In the range of 0.01 - 0.11 mJ/mm2	Values of ultrasonic pulse: 5bar/0.284mJ/mm2 3bar/0.176mJ/mm2	0.29 mJ/mm2 at 4 bar 0.14 mJ/mm2 at 2.4 bar	**Not Significantly different**
Operating mode	Continuous	Continuous	Continuous	**None**

Projectile mass (g)	N/A	3	3.2	**Not applicable** The BTL-094 applicator does not contain a projectile.
Pulse repeat rate (1/s)	1-25 Hz	1-21Hz	1-25 Hz	**Not Significantly different**
Number of pulses (min and max)	Variable in range 0 - 9999	Variable	Variable, Max 5000/treatment	**Not Significantly different**
Maximum operating temperature	10 - 35 °C	10-40°C	10 - 30 °C	**Not Significantly different**
Type of acoustic wave generation	Electroacoustic technology with electroacoustic lens system	Pneumatic/ballistic	Pneumatic/ballistic	**Not Significantly different** Differences are caused by alternative technology of the pressure wave generation.
Positive peak pressure amplitude (MPa)	In the range of 3 - 10 MPa	Values of ultrasonic pulse: 5bar/18.5MPa 3bar/13.4MPa	17 MPa at 4 bar 11.24 MPa at 2.4 bar	**Not Significantly different** Please see the discussion and conclusion below.
Negative peak pressure amplitude (MPa)	In the range of 3 - 10 MPa	Values of ultrasonic pulse: 5bar/6.8MPa 3bar/5.0MPa	10 MPa at 4 bar 7.2 MPa at 2.4 bar	**Not Significantly different** Please see the discussion and conclusion below.
Derived focal acoustic pulse energy (mJ)	In the range of 0.1 – 1.4 mJ	Values of ultrasonic pulse: 5bar/6.5mJ 3bar/2.4mJ	5.9 mJ at 4 bar* 2.2 mJ at 2.4 bar* *Averaged across all applicator sizes.	**Not Significantly different** Please see the discussion and conclusion below.
Derived pulse-intensity integral, integrated over total temporal integration limits (mJ/mm2)	In the range of 0.01 - 0.11 mJ/mm2	Values of ultrasonic pulse: 5bar/0.284mJ/mm2 3bar/0.176mJ/mm2	0.29 mJ/mm2 at 4 bar 0.14 mJ/mm2 at 2.4 bar	**Not Significantly different** Please see the discussion and conclusion below.
Rise time (ns)	10 ns	Ultrasonic pulse: 2.5µs	3.2 µs	**Not Significantly different**

		Sonic pulse: 25µs – 2.5ms		Differences are caused by alternative technology of the energy generation.
Compressional pulse duration (µs)	2µs	Ultrasonic pulse: 5.0µs Sonic pulse: 50µs – 5.0ms	2.6 µs (1st peak) 62.7 µs (1st phase)	**Not Significantly different**

Modes of Action, Mechanisms of Action
The technology used in BTL-094 device differs from the predicate device. Nevertheless, the technology creates the same type of acoustic pressure delivered to the tissue. Similar devices that generate a pressure wave based on a different technological principle but with the same or very comparable mechanism of action have already been recognised as substantially equivalent in this device category.

Maximum and Minimum intensity settings
BTL-094 has an alternative type of technology from the predicate device and therefore the BTL-094 device has an alternative power setting scale - in percentage and not in bars as a comparative device has. In addition, for comparability with the predicate devices the BTL-094 device intended for the US market is limited to a maximum power level of 30% of maximum driving power.

Number and size of treatment applicator heads
The number of application pads are different from predicate device but the area of the subjected device pads that is in contact with the patient is comparable within a set range to the contact area of application tips of predicate devices. Additionally all materials in contact with patient have been assessed for biocompatibility and the maximal depth of pressure wave penetration is comparable to the predicate.

Maximum and minimum displacements of applicator heads
The predicate device is generating the pressure wave by the head displacement. Due to an alternative type of technology used for pressure wave generation the BTL-094 device does not have the ability of displacements of applicator heads/pads.

Maximum and minimum vibration frequency
BTL-094 device differs from one predicate device in the value of the maximum frequency, where the frequency value of the BTL-094 device can be up to 4Hz higher than the predicate device, but has available the same frequency range as its second predicate device.

Driving Power
BTL-094 device has an alternative type of technology from the predicate device and therefore the driving power parameter is not applicable. In addition, for comparability with the predicate devices the BTL-094 device intended for the US market is limited to a maximum power level of 30% of maximum driving power.

Energy flow density
BTL-094 device uses alternative technology and is able to better pulse targeting, a maximum driving power of the device has been limited at a maximum power level of 30%. The EFD of our device differs from the predicates but it is lower or within setting range of predicat devices.

Operating mode
The BTL-094 device has two modes of operation: single therapy mode or sequence mode. The two modes differ based on repetition of therapy sections and settings that can be done during the running therapy. Nevertheless, both the modes have a character of continual therapy.

Maximum penetration depth
The BTL-094 device is equipped with two different coupling pad sizes, which allow it to reach up to 35 mm depth. This penetration depth is comparable within setting range of predicate devices.

Pulse repeat rate (1/s)
BTL-094 device differs from one predicate device in the value of the maximum frequency, where the frequency value of the BTL-094 device can be up to 4Hz higher than the predicate device, but has available the same frequency range as its second predicate device.

Number of pulses (min and max)
BTL-094 device allows to set a variable number of pulses according to the user's needs. This parameter is similar as for the predicate device.

Type of acoustic wave generation
The subject device provides the therapy by the application of extracorporeally induced acoustic pressure waves that are generated by means of piezoelectric principle. The device is designed with planar piezo-element and acoustic lens guiding the waves. The generated wave is coupled to biological tissue via the coupling gel pads of the applicator.

This technology creates the same type of acoustic pressure wave with comparable parameters therefore it reach the same mechanism of action as the predicate devices.

Positive peak pressure amplitude (MPa)
A maximum driving power of the BTL-094 has been limited at a maximum power level of 30%. The device with this limitation in maximal output power fits with output parameters within or bellow setting range of predicat devices and is not significantly different from the predicate devices.

Negative peak pressure amplitude (MPa)
A maximum driving power of the BTL-094 has been limited at a maximum power level of 30%. The device with this limitation in maximal output power fits with output parameters within or bellow setting range of predicat devices and is not significantly different from the predicate devices.

Derived focal acoustic pulse energy (mJ)
A maximum driving power of the BTL-094 has been limited at a maximum power level of 30%. The device with this limitation in maximal output power fits with output parameters within or bellow setting range of predicat devices and is not significantly different from the predicate devices.

Derived pulse- intensity integral, integrated over total temporal integration limits (mJ/mm2)
A maximum driving power of the BTL-094 has been limited at a maximum power level of 30%. The device with this limitation in maximal output power fits with output parameters within or bellow setting range of predicat devices and is not significantly different from the predicate devices.

Rise time (ns)
BTL-094 has an alternative type of technology from the predicate device and therefore the BTL-094 device is able to reach a faster rise time and shorter compressional pulse duration.

Compressional pulse duration (µs)
BTL-094 has an alternative type of technology from the predicate device and therefore the BTL-094 device is able to reach a faster rise time and shorter compressional pulse duration.

Substantial Equivalence

The BTL-094 is substantially equivalent to the predicate devices D-Actor (K173692) and DolorClast® Radial (K220538). The subject device is safe and effective for its intended use.

Any differences between the predicate devices and BTL-094 have no significant influence on the safety or effectiveness of the subject device. Therefore, the BTL-094 is substantially equivalent to the predicate devices.

Conclusion

Based upon the intended use and known technical information provided in this pre-market notification, the BTL-094 device has been shown to be substantially equivalent to the currently marketed predicate device.