April 23, 2024

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

Re: K233849
Trade/Device Name: Btl-499
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, PBX
Dated: March 28, 2024
Received: March 28, 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.04.23 15:50:17 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*

Device Name

BTL-499

Indications for Use *(Describe)*

BTL-499 is indicated to be used for:
Non-invasive lipolysis (breakdown of fat) of the abdomen.
Reduction in circumference of the abdomen.
Non-invasive lipolysis (breakdown of fat) of the thighs.
Reduction in circumference of the thighs.
BTL-499 is intended for use with skin types I – VI.
Non-invasive lipolysis (breakdown of fat) of the flanks limited to skin types I - IV.
Non-invasive lipolysis (breakdown of fat) of the upper arms limited to skin types II and III and BMI 30 and under.

The BTL-499 is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The BTL-499 massage function is intended to provide a temporary reduction in the appearance of cellulite.

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

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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:	November 20, 2023

Device

Trade/Proprietary Name:	BTL-499
Primary Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Regulation:	21 CFR 878.4400, Class II
Classification Product Code:	GEI, PBX

Legally Marketed Predicate Device

The BTL-499 is a state-of-the-art high-frequency energy device with accessories, and is substantially equivalent to the following products that are already cleared for distribution in the USA under the following 510(k) Premarket Notification numbers:

BTL-899F
Original 510(k) Sponsor: BTL Industries, Inc.
510(k) Number: K230467

BTL-785X
BTL-785-1 applicator and BTL-785-1-4 attachment
Original 510(k) Sponsor: BTL Industries Inc.
510(k) Number: K222556

Product Description

The BTL-499 is a non-invasive therapeutic device. The device is comprised of a main unit and applicators that deliver energy to the targeted tissue. The device's two outputs enable hands-free simultaneous treatment by two applicators.

The BTL-499 is equipped with a large color touch-screen that significantly 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 easily 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.

Technological characteristics

The BTL-499 device has similar technological characteristics compared to its predicate devices. The BTL-499 device and the predicates are comprised of a system console and applicators.

The system console consists of the RF, HV and massage generators, computer, and a touch-screen control panel. The system combines bipolar radiofrequency with electromagnetic stimulation and mechanical massage. The device is accompanied by the following applicators: 499-AP-MRA-1, 499-AP-MR-2, 499-AP-MRA-4 & 499-AP-MRA-5

Indications for Use

BTL-499 is indicated to be used for:

- Non-invasive lipolysis (breakdown of fat) of the abdomen.
- Reduction in circumference of the abdomen.
- Non-invasive lipolysis (breakdown of fat) of the thighs.
- Reduction in circumference of the thighs.
- BTL-499 is intended for use with skin types I – VI.

- Non-invasive lipolysis (breakdown of fat) of the flanks limited to skin types I - IV.
- Non-invasive lipolysis (breakdown of fat) of the upper arms limited to skin types II and III and BMI 30 and under.

The BTL-499 is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The BTL-499 massage function is intended to provide a temporary reduction in the appearance of cellulite.

Non-clinical Testing (Performance, Bench Testing)

The BTL-499 device has been thoroughly evaluated for electrical safety. 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 disturbances – 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

Clinical Testing

Not applicable to this submission

Comparison with the Predicate Device

510(k) number **Device name** **Company name**	**Not assigned** BTL-499 BTL Industries, Inc.	**K230467** BTL-899F BTL Industries, Inc.	**K222556** BTL-785X with BTL-785-1 & BTL-785-1-4 BTL Industries, Inc.
Product Code and Regulation	General & Plastic Surgery 21 CFR 878.4400 GEI – Electrosurgical, Cutting & Coagulation & Accessories PBX – Massager, Vacuum, Radiofrequency Induced Heat	General & Plastic Surgery 21 CFR 878.4400 GEI - Electrosurgical, Cutting & Coagulation & Accessories	General & Plastic Surgery 21 CFR 878.4400 GEI – Electrosurgical, Cutting & Coagulation & Accessories PBX – Massager, Vacuum, Radiofrequency Induced Heat
Indications for Use	BTL-499 is indicated to be used for: ● Non-invasive lipolysis (breakdown of fat) of the abdomen. ● Reduction in circumference of the abdomen. ● Non-invasive lipolysis (breakdown of fat) of the thighs. ● Reduction in circumference of the thighs. ● BTL-499 is intended for use with skin types I – VI. ● Non-invasive lipolysis (breakdown of fat) of the flanks limited to skin types I - IV. ● Non-invasive lipolysis	BTL-899F is indicated to be used for: ● Non-invasive lipolysis (breakdown of fat) of the abdomen. ● Reduction in circumference of the abdomen. ● Non-invasive lipolysis (breakdown of fat) of the thighs. ● Reduction in circumference of the thighs. ● BTL-899F is intended for use with skin types I – VI. ● Non-invasive lipolysis (breakdown of fat) of the flanks limited to skin types I - IV. ● Non-invasive lipolysis	The BTL-785X device has the following indications for use: The BTL-785X with BTL-785-1 applicator is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The BTL-785-1-4 massage device is intended to provide a temporary reduction in the appearance of cellulite.

	(breakdown of fat) of the upper arms limited to skin types II and III and BMI 30 and under. The BTL-499 is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The BTL-499 massage function is intended to provide a temporary reduction in the appearance of cellulite.	(breakdown of fat) of the upper arms limited to skin types II and III and BMI 30 and under	
Electrical Protection	Class II, BF	Class II, BF	Class II, BF
Clinical Use	Prescription use	Prescription use	Prescription use
Interface	Touch screen	Touch screen	Touch screen
Type of Energy	The system combines bipolar radiofrequency with electromagnetic stimulation and mechanical massage.	The system combines bipolar radiofrequency with electromagnetic stimulation.	The system combines radiofrequency with mechanical massaging of body parts with massage attachment.
Source of electro-magnetic stimulation	Single magnetic coil	Single magnetic coil	N/A
Number of output channels	2	2	N/A
Color Touch Screen	15.6 in 39.6 cm 1920x1080 pixels	15.6 in 39.6 cm 1920 x 1080 px.	15.6 in 39.6 cm 1920x1080 pixels

Type of Operation	Continuous	Continuous	Continuous
Pulse Repetition Rate - supported by the device	1 – 150 Hz	1 – 150 Hz	N/A
Magnetic Field Intensity	499-AP-MRA-1 - 0.5 to 1.8 T 499-AP-MR-2 - 0.7 to 2.0 T 499-AP-MRA-4/5 - 0.35 to 1.3 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	N/A
Pulse Duration	499-AP-MRA-1 – 255 µs ± 20% 499-AP-MR-2 - 190 µs ± 20% 499-AP-MRA-4/5 – 245 µs ± 20%	AP-C-1 - 280 µs ± 20 AP-C-2 - 190 µs ± 20% AP-C-4/5 - 260 µs ± 20%	N/A
Pulse Amplitude	0–100 %	0–100 %	N/A
Shape of Stimulation Pulse	Sine, biphasic	Sine, biphasic	Sine, biphasic
Type of Pulse	bipolar	bipolar	Monopolar
Max. RF Power	60W (2x30 W)	60W (2x30 W)	140W
RF Frequency	27.12 Mhz	27.12 Mhz	3.2 MHz
Temperature Sensor	Yes	Yes	Integrated thermometer + patient's feedback
Selection of parameters (Intensity, Time)	Yes	Yes	Yes

Types of applicators	3	3	1
Therapy Time	Up to 30 min	Up to 30 min	Up to 30 min
Application	Hands-free, applicator fixed by fixation belt	Hands-free, applicator fixed by fixation belt	Manual application of the therapy and massage
Massage frequency	0 – 40Hz	N/A	Manual application via attached massage device
Massage intensity	0 - 100%	N/A	Manual application via attached massage device
Energy Source	100 – 240 V AC, 50–60 Hz	100 – 240 V AC, 50–60 Hz	100-120 V AC / 200-240 V AC, 50/60 Hz
System Dimensions	23 x 52 x 35 in (593 x 1313 x 894 mm)	23 x 39 x 29 in (592 x 985 x 730 mm)	26 x 26 x 54 in (670 x 670 x 1370 mm)
System Weight	76 kg	85 kg	65 kg
Operating Ambient Temperature	+10°C to +30°C	+10°C to +30°C	+18 °C to +30 °C
Operating Relative Humidity	30% to 75%	30% to 75%	30% to 75%
Environmental Specifications	For indoor use only In vertical position – On castors	For indoor use only In vertical position – On castors	For indoor use only In vertical position – On castors

Substantial Equivalence

The BTL-499 device has the same intended use as its predicate devices. The technological characteristics of the predicate devices are similar to the BTL-499 device. Any differences between the predicate devices and BTL-499 have no significant influence on safety and effectiveness of the BTL-499 device. Therefore, the BTL-499 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-499 device has been shown to be substantially equivalent to currently marketed predicate devices.