January 26, 2021

BTL
David Chmel
Vice President of Operations
362 Elm Street
Marlborough, Massachusetts 01752

Re: K202199
Trade/Device Name: BTL-899ST
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 15, 2020
Received: December 18, 2020

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,

Long Chen, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202199

Device Name
BTL-899ST

Indications for Use *(Describe)*

BTL-899ST 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-899ST is intended for use with Skin Type I, II and III.

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:	26 January 2020

Device Name

Trade/Proprietary Name:	BTL-899ST
Primary Classification Name:	Electrosurgical, Cutting & Coagulation Device & Accessories
Classification Regulation:	878.4400, Class II
Classification Product Code:	GEI

Legally Marketed Predicate Device

The BTL-899ST is a state-of-the-art high-frequency 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:

- BTL-899 (K192224)

Product Description

The BTL-899ST is a non-invasive therapeutic device.

BTL-899ST consists of a main unit and applicator(s). The main unit is equipped with a color touch screen that makes the device easy to use. The on-screen information guides the Operator through the entire therapy procedure. The therapeutic parameters are easily set using the touch screen. During therapy, the screen displays information about the remaining therapy time and other therapy parameters. The device is equipped with the Total Stop Button to terminate the device. The Total Stop Button is located on the rear panel of the main unit. The two outputs (applicators) of the device enable hands-free simultaneous treatment by two applicators.

Indications for Use

BTL-899ST 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-899ST is intended for use with Skin Type I, II and III.

Non-clinical Testing (Performance, Bench Testing)

The BTL-899ST 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 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

A clinical study has been conducted to demonstrate the performance, clinical efficacy and safety of the BTL-899ST device for non-invasive lipolysis and circumference reduction of thighs. The treatment with the BTL-899 device has shown to be both effective and safe for non-invasive lipolysis and circumference reduction of the thighs.

In total, N=40 subjects were enrolled/treated in the study to be treated with BTL-899ST. N=29 subjects received treatment with the device and completed the 1-month follow-up and 38 subjects in total respected the 3- months follow-up and were examined and interviewed for possible adverse events.

All the subjects were female (average age 40.26) with 17 Fitzpatrick Skin Type (FST) II and 9 with FST III, and with 3 subjects having FST IV.

The primary efficacy outcome measure was a minimum of 80% of subjects at 30-day follow-up evaluation to show thighs mean circumference reduction of ≥ 1 cm relative to the baseline assessment.

Twenty-two of the twenty-nine subjects responded to treatment with the subject device. Forty-seven of the total 58 thighs treated had circumference reduction of ≤ 1 cm at 1-month follow-up relative to the baseline assessment.

All the twenty-nine subjects were either satisfied (9) or very satisfied (20) with the treatment results.

The participants also rated the improvement of their thighs at 1-month follow-up, with results leaning towards much improved.

The secondary endpoint was met with 100% of the participants in this satisfied with the therapy results. Furthermore, 90% of the subjects judged that the appearance of their thighs has been improved.

All the subjects found the therapy comfortable. Eight participants (28%) agreed and 21 (72%) strongly agreed with the statement „I found the treatment comfortable“.

A pain rating scale ranging from zero (no pain) to 10 (worst possible pain) was used. Ten persons (34%) reported weak pain. Nineteen subjects (66%) reported no pain at all by choosing a score of zero.

The below table is a summary of the study design and results:

Study design	Two-arm, open-label, interventional study
Sample size	29 subjects completed follow-up
Number of treatments and follow-up visits	4 treatments and 2 follow-up visits at 30 and 90 days.
Primary endpoints	The primary efficacy outcome measure was a minimum of 80% of subjects at 30-day follow-up evaluation to show mean thighs circumference reduction of ≥ 1 cm relative to the baseline assessment.
Secondary endpoints	Evaluation of the safety of the BTL-899 device for non-invasive lipolysis (breakdown of fat) of the thighs. Minimum 80% of treated subjects to report satisfaction (level satisfied and higher) with the therapy.
Efficacy Results	Twenty-two of the 29 subjects responded to treatment with the subject device. Forty-seven of the total 58 thighs treated had circumference reduction of ≤ 1 cm at 1-month follow-up relative to the baseline assessment.
Safety results	One adverse event was recorded. A participant in ARM 1 was diagnosed with panniculitis on the inner side of one of the thighs. The AE was judged as related to the treatment and was mild.

In conclusion, treatment with the BTL-899ST device has shown to be both effective and safe for non-invasive lipolysis and circumference reduction of thighs.

Based on the clinical data of above mentioned clinical study, the BTL-899ST device demonstrated acceptable performance and safety profile of the device for non-invasive lipolysis and circumference reduction of thighs. Results further support substantial equivalence of the subject device compared to the predicate device.

Technological Characteristics

The BTL-899ST device has the same intended use and identical technological characteristics and principles of operation to its predicate device. The BTL-899ST 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 mechanism of action and technological similarities and differences between the BTL-899ST device and the predicate device 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**	**K202199** BTL-899ST BTL Industries, Inc.	**K192224** BTL-899 BTL Industries, Inc.	**Significant Difference**
Product Code and Regulation	General & Plastic Surgery 21 CFR 878.4400 GEI - Electrosurgical, Cutting & Coagulation & Accessories	General & Plastic Surgery 21 CFR 878.4400 GEI - Electrosurgical, Cutting & Coagulation & Accessories	**None**
Indications for Use	BTL-899ST 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-899ST is intended for use with Skin Type I, II and III.	BTL-899 is indicated to be used for: ● Non-invasive lipolysis (breakdown of fat) of the abdomen. ● Reduction in circumference of the abdomen ● The BTL-899 is intended for use with Skin Type I to Skin Type III.	**Not significantly different**
Basic Technology	The system combines bipolar radiofrequency with electromagnetic stimulation.	The system combines bipolar radiofrequency with electromagnetic stimulation.	**None**
Clinical Use	Prescription use	Prescription use	**None**
Electrical Protection	Class II, BF	Class II, BF	**None**
User Interface	Touch screen	Touch screen	**None**

Firmware Controlled	Yes	Yes	**None**
Number of outputs channels	2	2	None
RF Type	bipolar	bipolar	**None**
Max. RF Power	60 W (2x30 W)	60 W (2x30 W)	**None**
RF Frequency	27.12 Mhz	27.12 Mhz	**None**
Number of Magnetic coils in the Applicator	1	1	None
Magnetic Field Intensity (on the coil surface)	0.5 to 1.8 T	0.5 to 1.8 T	None
Pulse Repetition Rate - supported by the device	1 – 150 Hz	1 – 150 Hz	None
Pulse Duration	280 µs ± 20% µs	280 µs ± 20% µs	None
Waveform	Biphasic	Biphasic	None
Shape	Sinusoidal	Sinusoidal	None
Temperature Sensor	Yes	Yes	**None**
Selection of parameters (Intensity, Time)	Yes	Yes	**None**
Application	Hands-free, applicator fixed by fixation belt	Hands-free, applicator fixed by fixation belt	**None**
Therapy Time	Up to 30 min	Up to 30 min	**None**
Energy Source	100 – 240 V AC, 50–60 Hz	100 – 240 V AC, 50–60 Hz	**None**
System Dimensions (W×H×D)	23 x 39 x 29 in (592 x 985 x 730 mm)	23 x 39 x 29 in (592 x 985 x 730 mm)	**None**
System Weight	85 kg	85 kg	**None**
Operating Ambient Temperature	+10°C to +30°C	+10°C to +30°C	**None**

Operating Relative Humidity	30% to 75%	30% to 75%	**None**
Environmental Specifications	For indoor use only	For indoor use only	**None**

Substantial Equivalence

The BTL-899ST device has expanded indications for use to include the thighs area.

There are no technological modifications done to the device and its applicator compared to the predicate device.

The Sponsor of this 510(k) submission has conducted a clinical study and based on the positive results achieved in the study the new indications have been added. Additionally, the safety of the device has been evaluated in the study and no new risks have been identified.

Therefore this difference does not raise any new questions of safety or effectiveness.

Conclusion

Based upon the intended use and the known technical and clinical data provided in this pre-market notification, the BTL-899ST device has been shown to be substantially equivalent to the currently marketed predicate device.