July 9, 2021

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

Re: K211107
Trade/Device Name: BTL-899 FP
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 12, 2021
Received: May 17, 2021

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)*

K211107

Device Name
BTL-899 FP

Indications for Use *(Describe)*

BTL-899 FP 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-899 FP is intended for use with skin type I - VI.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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:	07 April 2021

Device Name

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

Legally Marketed Predicate Device

The BTL-899 FP 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-899ST (K202199)

Product Description

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

BTL-899 FP 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 an emergency button to terminate the therapy. The two outputs (applicators) of the device enable hands-free simultaneous treatment by two applicators.

Indications for Use

BTL-899 FP 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-899 FP is intended for use with skin types I - VI.

Non-clinical Testing (Performance, Bench Testing)

The BTL-899 FP 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

BTL Industries conducted two clinical investigations in the United States of America.

In total 34 subjects with Fitzpatrick Skin Types (FST) IV-VI were recruited to participate in the two IRB-approved clinical studies investigating clinical efficacy and safety of the BTL-899 FP device for toning of abdomen and reduction of subcutaneous fat.

In summary 9 subjects with skin type IV, 8 subjects with skin type V and 8 subjects with skin type VI finished three active 30-minute treatments with BTL-899 FP device spaced 1 week apart. Average BMI of all subjects was 27.7±3.3 kg·m2. They were scheduled to 1-month, 3-month and 6-month follow-up (optional) visits and examined for adverse reactions to the treatment, fat tissue reduction (by diagnostic ultrasound or magnetic resonance), abdominal circumference reduction, therapy comfort (using 5-point Likert scale questionnaire and 10-point visual analogue scale - VAS) and subjective satisfaction (using 5-point Likert scale questionnaire).

The primary endpoint in subjects with FST IV-VI, who underwent active treatments with the BTL-899 FP device has been met. All subjects exhibited reduction in the fat thickness in their abdominal area, matching the efficacy previously evidenced in the 510(k) K192224. Circumference reduction was seen in 75% of subjects in total.

The secondary endpoint of the study, subjects' satisfaction with the therapy, has also been met with 88% of the subjects satisfied with the achieved results. Subjects felt none (92%) to minimal (8%) discomfort during the study treatment.

No adverse events were reported in the course of the clinical investigations and in particular in the subjects with FST IV-VI. There was no inflammation or post-inflammatory hyperpigmentation in the treated areas immediately after the treatments or at the follow-up visits. The only observed side effects related to the therapy were mild erythema and muscle soreness that occur in FST I-III subjects as well. These resolved very quickly for all subjects.

In conclusion, the treatments with BTL-899 FP have proven to be safe for patients with Fitzpatrick skin types I to VI.

Technological Characteristics

The BTL-899 FP device has the same intended use and identical technological characteristics and principles of operation to its predicate device. The BTL-899 FP 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-899 FP 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**	**Not assigned** BTL-899 FP BTL Industries, Inc.	**K202199** BTL-899ST 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-899 FP 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-899 FP is intended for use with skin types I - VI.	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.	**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 output 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	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 V to 230 V AC, 50 Hz 100 V to 130 V AC, 60 Hz	100 V to 230 V AC, 50 Hz 100 V to 130 V AC, 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	155 lb (70 kg) / 200 lb (91 kg) including packaging and accessories	155 lb (70 kg) / 200 lb (91 kg) including packaging and accessories	**None**
Operating Ambient Temperature	64 °F to 86 °F (+18 °C to +30 °C)	64 °F to 86 °F (+18 °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-899 FP device has expanded indications for use to include Fitzpatrick Skin Types I - VI.

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

The safety of the device has been evaluated and no new risks have been identified.

Therefore these differences do 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-899 FP device has been shown to be substantially equivalent to the currently marketed predicate device.