September 21, 2023

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

Re: K230467
Trade/Device Name: BTL-899F
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 17, 2023
Received: August 23, 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.09.21 13:17:11 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230467

Device Name
BTL-899F

Indications for Use *(Describe)*

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 (breakdown of fat) of the upper arms limited to skin types II and III and BMI 30 and under.

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	September 20, 2023

Device Name

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

Legally Marketed Predicate Device

The BTL-899F 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-899A (K213344)

Product Description

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

BTL-899F consists of a main unit and applicators. 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.

Indications for Use

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 (breakdown of fat) of the upper arms limited to skin types II and III and BMI 30 and under.

Non-clinical Testing (Performance, Bench Testing)

The BTL-899F 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 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 investigation has been conducted in order to study the effect of the device for non-invasive lipolysis on human flanks.

The primary objective of the study was to gather clinical evidence that the BTL-899 device, equipped with applicators 899-AP-C-4 & 899-AP-C-5, is capable of inducing non-invasive lipolysis on human flanks. A mean population reduction of flanks' fat thickness pre- vs 3-months post-treatment had to be observed.

The secondary objectives of the study were to evaluate the safety of the BTL-899 device for non-invasive lipolysis (breakdown of fat) of the flanks as well as to assess the participants' satisfaction and level of comfort. A minimum 75% of the subjects' pre-treatment and 3-month follow-up post-treatment images had to be correctly identified by at least two of three independent blinded evaluators.

The clinical investigation used a single-arm, open-label, interventional design. Fifty-five (55) subjects were enrolled to the study. Fifty-one (51) participants attended the final 3-month follow-up.

A mean population reduction of flanks' fat thickness pre- vs 3 months post-treatment was observed and the results showed 5 mm reduction in the mean fat thickness.

The primary endpoint was met.

- The average fat thickness reduction measured by the ultrasound was 5 mm

The secondary endpoints were met.

- The procedure with the device for non-invasive lipolysis of flanks was considered as safe. Only one anticipated side effect of the procedure was observed in one patient: A participant reported mild erythema lasting 1 hour after the second procedure that resolved itself without medical intervention. Erythema is an expected and declared side effect in the operator's manual due to the nature of the technology used for the procedure.

- All three independent blinded evaluators identified pre-treatment and 3-month follow-up images with more than 75% accuracy. The rate of successful recognition of the subject's pre-/post treatment photographs was 88.2%.

- The procedure was found comfortable and virtually painless. All the participants in the trial agreed or strongly agreed with the procedures being comfortable. All the participants were satisfied or very satisfied with the procedure at the 3-month follow-up. All the participants reported improved, much improved, or very much improved appearance of the flanks area at the 3-month follow-up.

Technological Characteristics

The BTL-899F device has the same intended use and identical technological characteristics and principles of operation to its predicate device. The BTL-899F 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-899F 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

	Predicate device	**Subject device**
510(k) number **Device name** **Company name**	**K213344** **BTL-899A** **BTL Industries, Inc.**	**K230467** **BTL-899F** **BTL Industries, Inc.**
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
Indications for Use	BTL-899A 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-899A is intended for use with skin types I - VI. ● Non-invasive lipolysis (breakdown of fat) of the upper arms limited to skin types II and III and BMI 30 and under	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 (breakdown of fat) of the upper arms limited to skin

		types II and III and BMI 30 and under
Basic Technology	The system combines bipolar radiofrequency with electromagnetic stimulation.	The system combines bipolar radiofrequency with electromagnetic stimulation.
Clinical Use	Prescription use	Prescription use
Electrical Protection	Class II, BF	Class II, BF
User Interface	Touch screen	Touch screen
Firmware Controlled	Yes	Yes
Number of output channels	2	2
RF Type	bipolar	bipolar
Max. RF Power	60 W (2x30 W)	60 W (2x30 W)
RF Frequency	27.12 Mhz	27.12 Mhz
Number of Magnetic coils in the Applicators	1	1
Magnetic Field Intensity (on the coil surface)	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	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
Pulse Repetition Rate - supported by the device	1 – 150 Hz	1 – 150 Hz
Pulse Duration	AP-C-1 - 280 µs ± 20% µs AP-C-2 - 190 µs ± 20% µs AP-C-4/5 - 260 µs ± 20% µs	AP-C-1 - 280 µs ± 20% µs AP-C-2 - 190 µs ± 20% µs AP-C-4/5 - 260 µs ± 20% µs
Waveform	Biphasic	Biphasic
Shape	Sinusoidal	Sinusoidal

Temperature Sensor	Yes	Yes
Selection of parameters (Intensity, Time)	Yes	Yes
Application	Hands-free, applicator fixed by fixation belt	Hands-free, applicator fixed by fixation belt
Therapy Time	Up to 30 min	Up to 30 min
Energy Source	100 – 240 V AC, 50–60 Hz	100 – 240 V AC, 50–60 Hz
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)
System Weight	85 kg	85 kg
Operating Ambient Temperature	+10°C to +30°C	+10°C to +30°C
Operating Relative Humidity	30% to 75%	30% to 75%
Environmental Specifications	For indoor use only	For indoor use only

Substantial Equivalence

The BTL-899F device has expanded indications for use based on positive results from clinical testing.

The predicate device BTL-899A (K213344) and the proposed device have identical mechanisms of action and technology.

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

Therefore these differences do not raise any 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-899F device has been shown to be substantially equivalent to the currently marketed predicate device.