December 5, 2019

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

Re: K192224
Trade/Device Name: BTL-899
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 1, 2019
Received: November 4, 2019

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192224

Device Name
BTL-899

Indications for Use *(Describe)*
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.

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

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:	December 4, 2019

Device Name

Trade/Proprietary Name:	BTL-899
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 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:

- SlimShape System (K163415)

Product Description

The BTL-899 is a non-invasive therapeutic device. The device is comprised of the main unit and applicators that deliver radiofrequency energy to the targeted tissue. The device two outputs enable hands-free simultaneous treatment by two applicators.

The BTL-899 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 keeps information about the applied therapy type, remaining therapy time and main therapy parameters on the screen.

Indications for Use

BTL-899 is indicated for non-invasive lipolysis (breakdown of fat) of the abdomen. The device is indicated for reduction in circumference of the abdomen. BTL-899 is intended for use with Skin Type I to Skin Type III.

Non-clinical Testing (Performance, Bench Testing)

The BTL-899 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

Clinical studies have been conducted to demonstrate performance, clinical efficacy and safety of the BTL-899 device for non-invasive lipolysis and circumference reduction of abdomen. The performance study has proven the device to reach and maintain effective treatment temperature.

Clinical efficacy study has proven that the therapy with the BTL-899 results in fat reduction of abdomen at the time of final therapy, and at one-month and three-month follow up.

In total, N=44 subjects were enrolled in the study. N=42 subjects received all treatments and finished the study. Of the 42 treated subjects, 29 are female and 13 are male. In terms of skin type treated, there are 5 subjects with Fitzpatrick Skin Type I, 29 with Fitzpatrick Skin Type II, 7 with Fitzpatrick Skin Type III and 1 with Fitzpatrick Skin Type IV.

Change in abdominal circumference at the last regular follow-up (3-month follow-up) visit was 3.2±1.64cm. Responder analysis showed 88.1% (74%, 96%) subjects had circumference reduction of 1.5cm and more when compared to baseline.

The secondary effectiveness endpoints demonstrated that the rate of correct identification of subjects' photographs was 76.19%.

Average fat reduction observed using the ultrasound images at the 3-month follow-up showed an average abdominal fat reduction of 29.8±3.38%.

Overall satisfaction with the study treatment was reported at all three regular follow-up visits, which was not the case at the therapy visits. 92.9% of subjects reported none to minimal discomfort during the study treatment.

Throughout the study, there were no adverse events reported. Observed side effects related to the therapy were mild erythema, muscle soreness, improved body posture and back pain relief.

The below table contains the study design and results:

Study design	Prospective open-label single-arm self-controlled study
Sample size	42 patients
Treatment and follow-up visits	There were three treatment visits and three follow-ups at one month, two months and three months after the last treatment.
Inclusion criteria	• Age > 21 years • Voluntarily signed informed consent form • BMI ≤ 35 kg/m^2 • Women of child-bearing potential were required to use birth control measures during the whole duration of the study

	• Subjects willing and able to abstain from partaking in any treatments other than the study procedure to promote body contouring during study participation • Subjects willing and able to maintain his/her regular (pre-procedure) diet and exercise regimen without effecting significant change in either direction during study participation
Endpoints	**Primary:** • Abdominal circumference reduction of at least 1.5cm at the 3-month follow-up visit when compared to baseline, evaluated using the tape measurement. • Evaluation of adverse events and side effects following the BTL-899 treatment throughout the study. **Secondary:** • Correct identification of baseline and 3-month follow-up visit photographs in at least 70% of treated subjects by two blinded evaluators. • Abdominal circumference reduction of at least 1.5cm at each study visit after the first treatment when compared to baseline, evaluated using the tape measurement. • Abdominal fat reduction at the last therapy visit, 1-month follow-up visit and 3-month follow-up visit when compared to baseline, evaluated using the ultrasound imaging device. • Subject's satisfaction with the BTL-899 treatment at each study visit after the first treatment assessed using the Subject Satisfaction Questionnaire. • Subject's discomfort (pain) level after each treatment evaluated using the Therapy Comfort Questionnaire.
Efficacy results	**Primary endpoint achieved**: abdominal circumference reduction of 1.5 cm and more after the last follow-up and when compared to baseline. **Secondary endpoints achieved:** • Both evaluators correctly identified subject's photographs in 76.19% of cases (N=32). • The average reduction in fat thickness measured at the time of the last regular follow-up visit (3 months after the last therapy)- the average fat reduction was by 29.8±3.38%. • The subjects reported overall satisfaction at all three follow-up visits (83.3%, 83.3% and 88.1% respectively). • At all three visits, 92.9% of subjects reported none to minimal discomfort during the study treatment.
Safety results	Throughout the whole study, there was no adverse event reported. One subject experienced mild erythema. Eleven subjects reported a feeling of muscle soreness after the study treatment. Additionally, during the study subjects reported an improved posture (7.1%) that resulted in a relief of back pain (N=2; 4.8%).

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

Histology data from a study of 8 subjects confirmed the safety and effectiveness of the device. The skin histological evaluations showed normal morphology of the dermal layer with no damage to keratinocytes, melanocytes, hair follicles, sweat or sebaceous glands.

According to the histology results, the primary objective of the trial was met. The investigational device induces non-invasive lipolysis (breakdown of fat) in the abdominal area. Therapy effects such as pyknotic nuclei and cell membrane degeneration leading to fat cell lysis and hence a decrease of the fat tissue were observed.

The Temperature Performance test shows that the therapy temperature of 40 – 43°C was achieved and maintained for the remaining therapy time. No adverse events occurred. The objectives of this performance test were met.

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

Technological Characteristics

The BTL-899 device has identical indications for use and similar technological characteristics and principles of operation to its predicate device. The BTL-899 device and its predicates are comprised of a system console and applicator(s). The system console consists of the generators, computer, and the touch-screen control panel.

Generated radiofrequency energy is intended to interact with the tissues of the human body to achieve non-invasive lipolysis and circumference reduction.

The mechanism of action and technological similarities and differences between the BTL-899 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 BTL Industries, Inc.	**K163415** SlimShape System Syneron Medical Ltd.	**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 is indicated to be used for: • Non-invasive lipolysis (breakdown of fat) of the abdomen. • Reduction in circumference of the abdomen	The SlimShape System is indicated for non-invasive lipolysis (breakdown of fat) of the abdomen. The device is indicated for reduction in circumference of the abdomen.	**None**
Basic Technology	The system combines bipolar radiofrequency with electromagnetic stimulation.	The system combines bipolar radiofrequency with mechanical suction.	**Not significantly different** Please see the discussion and conclusion.
Clinical Use	Prescription use	Prescription use	**None**
Electrical Protection	Class II, BF	Class I, Type BF	**Not significantly different** Please see the discussion and conclusion.
User Interface	Touch screen	Touch screen	**None**
Firmware Controlled	Yes	Yes	**None**

RF Type	bipolar	bipolar	**None**
Max. RF Power	60 W (2x30 W)	80 W	**Not significantly different** Please see the discussion and conclusion.
RF Frequency	27.12 Mhz	1 Mhz	**Not significantly different** Please see the discussion and conclusion.
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	110 – 230 V AC, 50-60 Hz	**Not significantly different**
System Dimensions (W×H×D)	23 x 39 x 29 in (592 x 985 x 730 mm)	19.6 x 40.7 x 20.7 in	**Not significantly different**
System Weight	85 kg	53 kg	**Not significantly different**
Operating Ambient Temperature	+10°C to +30°C	+10°C to +30°C	**Not significantly different**
Operating Relative Humidity	30% to 75%	30% to 80%	**Not significantly different**

Environmental Specifications	For indoor use only	For indoor use only	**None**

Substantial Equivalence

The BTL-899 device is indicated to be used for non-invasive lipolysis (breakdown of fat) of the abdomen and reduction in circumference of the abdomen, as in the SlimShape System predicate (K163415). The BTL-899 device uses bipolar radiofrequency similar to the SlimShape System.

The main difference between the SlimShape System and the BTL-899 is in used frequency, maximal power and energy type enhancing the blood flow and lymphatic drainage. The emitting frequency of the BTL-899 is higher (27.12Mhz) compared to the SlimShape System predicate (1Mhz). Maximal radiofrequency power of the BTL-899 is lower than the one by the predicate device. The SlimShape System uses mechanical suction through vacuum, while the BTL-899 applies muscle stimulation resulting in induced muscle workout. Muscle workout naturally increases local blood circulation and lymphatic drainage.

The results of clinical data indicate that the BTL-899 device is able to achieve equivalent treatment temperature and maintain it for required time. The data from clinical study indicate that the device is both effective and safe for non-invasive lipolysis and circumference reduction of abdomen.

Any differences between the predicate device and BTL-899 have no significant influence on safety or effectiveness of the BTL-899 device. Therefore, the BTL-899 is substantially equivalent to the predicate device.

Conclusion

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