August 21, 2020

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

Re: K193201
Trade/Device Name: BTL-785F
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI, PBX
Dated: May 21, 2020
Received: May 26, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193201

Device Name
BTL-785F

Indications for Use *(Describe)*

The BTL-785F device has the following indications for use:
The BTL-785F 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.
The BTL-785F with BTL-785-2 applicator is indicated 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-785F with BTL-785-3 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 Applicator BTL-785-4 of BTL-785F device used with tips BTL-785-4-1, BTL-785-4-2, BTL-785-4-5 and BTL-785-4-6 is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.
The Applicator BTL-785-4 of BTL-785F device used with tips BTL-785-4-3, BTL-785-4-4, BTL-785-4-7 and BTL-785-4-8 is intended for dermatological procedures requiring fractional treatment of the skin. At higher energy levels greater than 62 mJ/pin, use of the BTL-785-4 applicator is limited to Skin Types I-IV.

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:	August 21, 2020

Device

Trade/Proprietary Name:	BTL-785F
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 Devices

The BTL-785F is a state-of-the-art radiofrequency device with accessories, and is substantially equivalent to the three current products that are already cleared for distribution in the USA under the following 510(k) Premarket Notification numbers:

- XP3000 (K150720)
- Exilis 5000 (K092191)
- BTL-FR2000 (K180359)

Product Description

The BTL-785F is a state-of-the-art radiofrequency device that enables the application of therapy by a high-frequency field.

The control unit of the system 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. For easier control, the hand-pieces are equipped with buttons, enabling operation of the device during therapy. The energy flow's quality is indicated by the illuminated treatment tip. The BTL-785F device comes with four different types of applicators.

The BTL-785F device consists of the following main components:

- microprocessor-driven control unit
- radiofrequency generator
- user interface with 15.6'' color touch screen
- applicators for an application of radiofrequency
- exchangeable applicator tips

Indications for Use

The BTL-785F device has the following indications for use:

The BTL-785F 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.

The BTL-785F with BTL-785-2 applicator is indicated 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-785F with BTL-785-3 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 Applicator BTL-785-4 of BTL-785F device used with tips BTL-785-4-1, BTL-785-4-2, BTL-785-4-5 and BTL-785-4-6 is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.
The Applicator BTL-785-4 of BTL-785F device used with tips BTL-785-4-3, BTL-785-4-4, BTL-785-4-7 and BTL-785-4-8 is intended for dermatological procedures requiring fractional treatment of the skin. At higher energy levels greater than 62 mJ/pin, use of the BTL-785-4 applicator is limited to Skin Types I-IV.

Performance Data

The BTL-785F 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 60601-2-2	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories
IEC 60601-2-5	Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment
IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
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 10993-7	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

ISO 10993-11	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
ISO 11135	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

Bench testing has been performed in order to demonstrate that the device is able to achieve and maintain therapeutic temperature on different treated areas for at least 10min.

Bench testing has been performed in order to demonstrate that the power output of the generator and geometry of the 785-4 applicator is identical to the same of the predicate.

Technological Characteristics

The BTL-785F device has similar technological characteristics compared to its predicate devices. The BTL-785F device and the predicates are comprised of a system console and applicator(s). The system console consists of the RF generator, computer, and the touch-screen control panel. The device is accompanied by four applicators enabling connection to exchangeable tips.

The compared devices' applicators use the RF signal of the same monopolar mode of operation, waveform and frequency. The maximum power intensity level of BTL-785F device in some cases differs to the predicates; nevertheless, based on the performance tests, the current device is able to reach the required treatment temperature and maintain it throughout the recommended treatment time. Therefore the current device is able to achieve substantial equivalent intended use based on identical mechanism of action.

The compared devices have similar properties regarding their RF tips, including material, size, biocompatibility properties and sterilization method where applicable.

The BTL-785F device is used with a larger neutral electrode compared to the predicate device. This approach prevents overheating and assures higher level of safety compared to the predicate device.

The differences do not raise any new questions of safety nor effectiveness.

Comparison with the Predicate Device

510(k) number **Device name** **Company name**	**K193201** BTL-785F BTL Industries, Inc.	**K150720** XP3000 BTL Industries, Inc.	**K092191** Exilis 5000 BTL Industries, Inc.	**K180359** BTL-FR2000 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 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
Indications for Use	The BTL-785F device has the following indications for use: The BTL-785F 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. The BTL-785F with BTL-785-2 applicator is indicated 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-785F with BTL-785-3 applicator is intended to provide heating for the purpose of elevating	The XP3000 device 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 XP3000 massage device is intended to provide a temporary reduction in the appearance of cellulite.	The EXILIS device is indicated for the primary treatment of dermatologic and general surgical procedures for non-invasive treatment of wrinkles and rhytids.	The Applicator 786-1 of BTL-FR2000 device is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis. The Applicator 786-2 of BTL-FR2000 device is intended for dermatological procedures requiring fractional treatment of the skin.

	tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The Applicator BTL-785-4 of BTL-785F device used with tips BTL-785-4-1, BTL-785-4-2, BTL-785-4-5 and BTL-785-4-6 is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis. The Applicator BTL-785-4 of BTL-785F device used with tips BTL-785-4-3, BTL-785-4-4, BTL-785-4-7 and BTL-785-4-8 is intended for dermatological procedures requiring fractional treatment of the skin. At higher energy levels greater than 62 mJ/pin, use of the BTL-785-4 applicator is limited to Skin Types I-IV.			
Principle of Action	Application of the heat to the tissue via RF energy. Massaging of body parts with massage attachment. (785-1 applicator only)	Application of the heat to the tissue via RF energy. Massaging of body parts with massage attachment.	Application of the heat to the tissue via RF energy. Massaging of body parts with massage attachment.	Delivering the RF energy through the skin results in an electro-thermal reaction. The heating effect causes collagen coagulation and encourages skin's natural healing process.
Clinical Use	Prescription use	Prescription use	Prescription use	Prescription use
Energy Source	100 – 120 V AC, 50/60 Hz 200 – 240 V AC, 50/60 Hz	100 – 240 V AC, 50 – 60 Hz	100-120 V AC, 5 A, 50/60 Hz 208-240 V AC, 2.5 A, 50 Hz	100 – 240 V AC, 50 – 60 Hz
Type of Energy Applied	Electromagnetic Energy – Radiofrequency	Electromagnetic Energy - Radiofrequency	Electromagnetic Energy - Radiofrequency	Electromagnetic Energy – Radiofrequency
Frequency	3.2 MHz ± 5% (BTL-785-1, BTL-785-2, and BTL-785-3)	3.25 MHz ± 50 kHz	3.25 Mhz ± 50 kHz	1 MHz ± 5%

	1 MHz ± 5% (BTL-785-4)			
Mode of Operation	Monopolar	Monopolar	Monopolar	Monopolar
User Interface	Color Touch-screen 15.6" 1920x1080 px	Color Touch-screen 8.4" 640×480 px	Color Touch-screen 8.4" 640×480 px	Color Touch-screen 8.4" 640×480 px
Maximum Output Power	125 W (BTL-785-1-2) 140 W (BTL-785-1-1) 62 W (BTL-785-2-1) 53 W (BTL-785-2-2) 62 W (BTL-785-2-3) 48 W (BTL-785-3-1) 30 W (BTL-785-4-1, 2, 5, 6) 25 W (BTL-785-5-4, 8) 20 W (BTL-785-4-3, 7)	120 W (215/3) 170 W (215/1)	170W	30 W (N1, N2) 25 W (P2) 20 W (P1)
Effective Treatment Temperature	40 - 45°C (104 – 113°F)	40 - 45°C (104 – 113°F)	39 - 42°C (102 - 108°F)	60 - 80°C (140°F-176°F)
Skin Temperature Monitoring	Integrated thermometer + patient's feedback (BTL-785-1, 2, 3)	Integrated thermometer + patient's feedback (Handpiece 215/1) Based on patient's feedback (Handpiece 215/3)	Skin temperature measurement	N/A
The Ultrasonic Tip Pre-heating Function	Yes (BTL-785-1, 2)	No	No	No
Massage Attachment	Yes (BTL-785-1)	Yes	Yes	No
Number of Microneedles	6 x 6	N/A	N/A	6 x 6
Depth of Microneedle Electrodes	0.5 – 4 mm	N/A	N/A	0.5 – 3.5 mm
Number of Pins of Superficial Tips	32	N/A	N/A	32
	64	N/A	N/A	64
Sterilization Method	Ethylene oxide	N/A	N/A	Ethylene oxide

Neutral Electrode Area	169 cm^2	118 cm^2	118 cm^2	118 cm^2
System Weight	60 kg (132 lb)	30 kg (66 lb)	15.3 kg (33.7 lb)	7.3 kg (16 lb)
System Dimension (W×H×D)	1370 mm x 670 x 670 (53.94" x 26.38" x 26.38")	1000 x 600 x 600 mm (39.37" x 23.62" x 23.62")	230 x 390 x 260 mm (9.06" x 15.35" x 10.24")	1000 x 600 x 600 mm (39.37" x 23.62" x 23.62")

Substantial Equivalence

The BTL-785F device has similar technological characteristics and intended use compared to the predicate devices. Any differences between the predicate devices and BTL-785F device have no significant influence on safety or effectiveness of the BTL-785F device. Therefore, the BTL-785F device is substantially equivalent to the predicate devices.

Conclusion

Based upon the intended use, comparison of technical characteristics and performance testing provided in this pre-market notification, the BTL-785F device has been shown to be substantially equivalent to currently marketed predicate devices for requested intended use.