March 7, 2022

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

Re: K211639
Trade/Device Name: BTL-785W
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI, PBX
Dated: October 28, 2021
Received: November 29, 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)*
K211639

Device Name
BTL-785W

Indications for Use *(Describe)*

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

The BTL-785W 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-785W 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-785W 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-785W 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.

The BTL-785-7 hands-free applicator of BTL-785W used with BTL-785-7-1, BTL-785-7-2, BTL-785-7-3 and BTL-785-7-4, BTL-785-7-5, BTL-785-7-6 single use electrodes 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.

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: March 4, 2022

Device

Trade/Proprietary Name:	BTL-785W
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 Device

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

- BTL-785F (K193201)
- EXILIS 5000 (K092191)
- TempSure System, (K200241), FlexSure single-use Applicator

Product Description

The BTL-785W 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-785W device comes with five different types of applicators.

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

The BTL-785W 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-785W 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-785W 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 BTL-785W with BTL-785-4 applicator 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-785W 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.

The BTL-785W with BTL-785-7 hands-free applicator used with BTL-785-7-1, BTL-785-7-2, BTL-785-7-3, BTL-785-7-4, BTL-785-7-5 and BTL-785-7-6 single-use electrodes 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.

Performance Data

The BTL-785W 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

BTL-785-7 applicator non-clinical performance data

The new BTL-785-7 applicator was tested to achieve superficial skin temperature (40 - 45°C) and maintain it for required therapy time. The testing data demonstrated that the device is capable to achieve therapeutic parameters substantially equivalent to the currently cleared predicate device for requested intended use.

Technological Characteristics

The BTL-785W device has similar technological characteristics compared to its predicate device. The BTL-785W device and the predicates are comprised of a system console and applicator(s). The system console consists of the RF generator, computer, and a 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 devices have the same properties regarding their RF tips, including material, size, biocompatibility and sterilization method where applicable.

Comparison with the Predicate Device

510(k) number **Device name** **Company name**	**K211639** BTL-785W BTL Industries, Inc.	**K193201** BTL-785F BTL Industries, Inc.	**K200241** TempSure System FlexSure single-use Applicator Cynosure, LLC Reference device	**Significant difference**
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 GEI – Electrosurgical, Cutting & Coagulation & Accessories PBX – Massager, Vacuum, Radiofrequency Induced Heat	General & Plastic Surgery 21 CFR 878.4400 GEI – Electrosurgical, Cutting & Coagulation & Accessories PBX – Massager, Vacuum, Radiofrequency Induced Heat	None
Indications for Use	The BTL-785W device has the following indications for use: The BTL-785W 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-785W with BTL-785-2 applicator is indicated to provide heating for the purpose of	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	The TempSure™ System has the following indications for use: The 10mm, 15mm, and 20mm Smart Handpieces are indicated for non-ablative treatment of mild to moderate facial wrinkles and rhytids. The 18mm, 25mm, 30mm, 60mm Smart Handpieces and FlexSure™ applicators provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain,	Not significant, please see discussion and conclusion below.

	elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The BTL-785W 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-785W 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-785W 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. The BTL-785W with BTL-785-7 hands-free applicator used with BTL-785-7-1, BTL-785-7-2, BTL-785-7-3, BTL-785-7-4, BTL-785-7-5 and BTL-785-7-6 single-use electrodes is intended to provide heating for the purpose of elevating tissue temperature for	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.	muscle spasms, and increase in local circulation. The massage device is intended to provide a temporary reduction in the appearance of cellulite	

	selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.			
Principle of Action	Application of the heat to the tissue via RF energy. Massaging of body parts with massage attachment. (785-1 applicator only) Radiofrequency accompanied by electromagnetic stimulation (785-7 applicator only)	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.	None
Clinical Use	Prescription use	Prescription use	Prescription use	None
Energy Source	100 – 120 V AC, 50/60 Hz 200 – 240 V AC, 50/60 Hz	100 – 120 V AC, 50/60 Hz 200 – 240 V AC, 50/60 Hz	100 – 120 V AC, 50/60 Hz 200 – 240 V AC, 50/60 Hz	None
Type of Energy Applied	Electromagnetic Energy – Radiofrequency	Electromagnetic Energy – Radiofrequency	Electromagnetic Energy – Radiofrequency	None
Frequency	3.2 MHz ± 5% (BTL-785-1, BTL-785-2, and BTL-785-3, BTL-785-7) 1 MHz ± 5% (BTL-785-4)	3.2 MHz ± 5% (BTL-785-1, BTL-785-2, and BTL-785-3) 1 MHz ± 5% (BTL-785-4)	4.0 MHz Sin-wave CW, Fully Rectified, Partially Rectified, and 1.7 MHz for Bipolar	Not significantly different
Mode of Operation	Monopolar	Monopolar	Monopolar, Bipolar	None
User Interface	Color Touch-screen	Color Touch-screen	Color Touch-screen	None
Maximum Output Power	125 W (BTL-785-1-2,) 140 W (BTL-785-1-1,)	125 W (BTL-785-1-2) 140 W (BTL-785-1-1)	300W (Surgical) 120W (Wrinkles) 300W (Tissue Heating)	Not significant, please see

	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 (BTL-785-7)	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)		discussion and conclusion below.
Effective Treatment Temperature	40 - 45°C	40 - 45°C	42 - 44°C	not significant
Skin Temperature Monitoring	Integrated thermometer + patient's feedback (BTL-785-1, 2, 3)	Integrated thermometer + patient's feedback (BTL-785-1, 2, 3)	Temperature-Sensitive Handpiece	None
Ultrasonic Tip Pre-heating Function	Yes (BTL-785-1, 2)	Yes (BTL-785-1, 2)	Yes	None
Massage Attachment	Yes (BTL-785-1)	Yes (BTL-785-1)	Yes	None
Number of Microneedles	6 x 6	6 x 6	N/A	None
Handsfree applicator	Yes	No	Yes	None
Depth of Microneedle Electrodes	0.5 – 4 mm	0.5 – 4 mm	N/A	None
Number of Pins of Superficial Tips	32	32	N/A	None
	64	64	N/A	None
Sterilization Method	Ethylene oxide	Ethylene oxide	N/A	None

Neutral Electrode Area	169 cm^2	169 cm^2	203 cm^2	not significant
System Weight	60 kg (132 lb)	60 kg (132 lb)	13.6 kg (30 lb) - generator weight only	not significant
System Dimension (W×H×D)	1370 mm x 670 x 670 (53.94" x 26.38" x 26.38")	1370 mm x 670 x 670 (53.94" x 26.38" x 26.38")	450 x 310 x 580 mm (18” x 12” x 22.5”)	not significant

Introduction of New Applicator BTL-785-7

This submission introduces the new applicator BTL-785-7. The BTL-785W with BTL-785-7 applicator used with BTL-785-7-1, BTL-785-7-2, BTL-785-7-3, BTL-785-7-4, BTL-785-7-5 and BTL-785-7-6 single-use electrodes 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.

Maximum RF and Output Power and EMS (BTL-785-7 applicator**)**

The maximum radiofrequency power as well as the maximum output power of the BTL-785-7 hands-free applicator is lower than the predicate. Nevertheless, the results of internal tests demonstrate that the device is able to achieve an equivalent treatment temperature and maintain it for the time required. The predicate device uses mechanical manipulation of the muscles, while the BTL-785-7 applies muscle stimulation resulting in induced muscle workout. Muscle workout naturally increases local blood circulation.

We believe the difference does not raise any new questions of safety or effectiveness.

Substantial Equivalence

The BTL-785W device has the same technological characteristics and similar intended use compared to the predicate device. Any differences between the predicate device and BTL-785W device have no significant influence on safety or effectiveness of the BTL-785W device.

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

Therefore, the BTL-785W 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-785W device has been shown to be substantially equivalent to currently cleared predicate device for requested intended use.