May 31, 2023

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

Re: K222556
Trade/Device Name: Btl-785x
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX, GEI
Dated: April 12, 2023
Received: May 3, 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: 2023.05.31 13:44:10 -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)*
K222556

Device Name
BTL-785X

Indications for Use *(Describe)*

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

The BTL-785X 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-785X 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-785X 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-785X 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-785X 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-785X with BTL-785-7 hands-free applicator used with forehead BTL-785-7-1 and cheek BTL-785-7-2 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.
- non-invasive temporary reduction of facial wrinkles

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

K222556

General Information

Sponsor: BTL Industries, Inc.
362 Elm Street
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Fax: +1-888-499-2502

Applicant: BTL Industries, Inc.
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Tel: +1-866-285-1656
Fax: +1-888-499-2502

Contact Person: David Chmel
BTL Industries, Inc.
chmel@btlnet.com

Summary Preparation Date: May 29, 2023

Device

Trade/Proprietary Name:	BTL-785X
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-785X 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-785W (K211639)
- EXILIS 5000 (K092191)

Product Description

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

The BTL-785X 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

Technological characteristics

The BTL-785X device has identical technological characteristics compared to its predicate device. The BTL-785X device and the predicate are comprised of a system console and applicators.

The system console consists of the RF generator, computer, and a touch-screen control panel. The device is accompanied by the following applicators:

- BTL-785-1 applicator providing treatment by integration of radiofrequency, ultrasound and active cooling. Suitable for the treatment of large body areas.
- BTL-785-2 applicator providing treatment by integration of radiofrequency and ultrasound. Suitable for the treatment of small areas.

- BTL-785-3 applicator providing radiofrequency treatment. The therapy is provided with single use tips only.
- BTL-785-4 applicator delivering radiofrequency via an array of microneedles and/or superficial pins. Therapy is provided with single use tips only.
- BTL-785-7 hands-free applicator providing treatment by integration of radiofrequency heating and muscle stimulation resulting in induced muscle workout. Muscle workout naturally increases local blood circulation. Suitable for the treatment of small and sensitive areas. The therapy is provided with single use electrodes only.

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.

Indications for Use

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

The BTL-785X 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-785X 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-785X 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-785X 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-785X 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-785X with BTL-785-7 hands-free applicator used with BTL-785-7-1 and BTL-785-7-2, 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.
- non-invasive temporary reduction of facial wrinkles.

Performance Data

The BTL-785X 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 clinical performance data

A clinical study was conducted to demonstrate the performance, clinical efficacy and safety of the BTL-785-7 hands-free applicator for non-invasive temporary reduction of wrinkles. This study has a single-center single-arm, open-label, interventional design.

The study was conducted at a single site. All the enrolled participants were treated with the BTL-785-7 hands-free applicator.

In total, N=42 subjects respected the study schedule and completed all the required study treatment visits and follow-up visits.

No adverse events occurred throughout the whole clinical investigation.

The study's primary efficacy endpoint was determined at the 3-month follow-up with three of the three blinded evaluators finding a statistically significant reduction of at least 1.0 score in the average score of FWES score at the 3-months follow-up compared to baseline. The average FWES score of the subjects showed an overall improvement of 1.44 points ($p<0.001$).

The overall satisfaction with the study treatment outcome was high with all forty-two participants (100%) either satisfied (N=14, 33.3%) or very satisfied (N=28, 66.7%) at the 3-month follow-up. None of the patients was dissatisfied. Furthermore, 100% of the subjects found the procedure comfortable.

Based on 3-month follow-ups, the treatment with the BTL-785X device equipped with applicator BTL-785-7 has shown to be both safe and effective for non-invasive temporary treatment of facial wrinkles with high satisfaction levels.

The below table is a summary of the study design and results:

Study design	Single-center single-arm, open-label, interventional design
Sample size	42 patients completed all study treatments and follow-up visits.
Number of treatments and follow-up visits	4 treatments and 2 follow-ups at 1 and 3 months
Primary endpoints	To gather clinical evidence that BTL-785 system equipped with the BTL-785-7 applicator is able to provide reduction of wrinkle severity according to the Fitzpatrick Wrinkle and Elastosis Scale. The primary efficacy outcome measure is a statistically significant reduction of at least 1.0 score in the average score of Fitzpatrick Wrinkle and Elastosis Scale score according to at least 2 out of 3 blinded dermatologists at 3-months follow-up compared to baseline.
Secondary endpoints	Evaluation of the safety of the BTL-785 device with BTL-785-7 applicator for non-invasive reduction of wrinkles The majority of the treated subjects to report satisfaction (level satisfied and higher) with the therapy.
Primary endpoint result	The average FWES score of the subjects showed an overall improvement of 1.44 points ($p<0.001$).
Secondary endpoint results	No adverse events were recorded by the investigator during this clinical investigation neither during treatments, nor in the follow-up period. All forty-two participants (100%) were either satisfied (N=14, 33.3%) or very satisfied (N=28, 66.7%) at the 3-month follow-up.

Comparison with the Predicate Device

510(k) number **Device name** **Company name**	**K222556** BTL-785X BTL Industries, Inc.	**K211639** BTL-785W BTL Industries, Inc.	**K092191** Exilis 5000 BTL Industries, Inc.
Type	Subject device	Primary predicate	Secondary predicate
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
Indications for Use	The BTL-785X device has the following indications for use: The BTL-785X 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	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	The EXILIS device is indicated for the primary treatment of dermatologic and general surgical procedures for non-invasive treatment of wrinkles and rhytids.

	temporary reduction in the appearance of cellulite. The BTL-785X 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-785X 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-785X 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.	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-785X 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-785X with BTL-785-7 hands-free applicator used with BTL-785-7-1, BTL-785-7-2, 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. • non-invasive temporary reduction of facial wrinkles.	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.	

Principle of Action	Application of the heat to the tissue via RF energy. Massaging of body parts with massage attachment. (BTL-785-1 applicator only) Radiofrequency accompanied by electromagnetic stimulation (BTL-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) Radiofrequency accompanied by electromagnetic stimulation (785-7 applicator only)	Application of the heat to the tissue via RF energy.
Clinical Use	Prescription use	Prescription use	Prescription use
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, 5 A, 50/60 Hz 208-240 V AC, 2.5 A, 50 Hz
Type of Energy Applied	Electromagnetic Energy – Radiofrequency	Electromagnetic Energy – Radiofrequency	Electromagnetic Energy - Radiofrequency
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, BTL-785-7) 1 MHz ± 5% (BTL-785-4)	3.25 Mhz ± 50 kHz N/A
Mode of Operation	Monopolar	Monopolar	Monopolar
User Interface	Color Touch-screen	Color Touch-screen	Color Touch-screen

Maximum Output Power	140 W (BTL-785-1-1) 62 W (BTL-785-2-1) 48 W (BTL-785-3-1) 30 W (BTL-785-4-1, 2, 5, 6) 25 W (BTL-785-4-4, 8) 20 W (BTL-785-4-3, 7) 39.8 W (BTL-785-7)	140 W (BTL-785-1-1) 125 W (BTL-785-1-2) 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-785-4-4, 8) 20 W (BTL-785-4-3, 7) 120 W (BTL-785-7)	170W
Effective Treatment Temperature	40 - 45°C (104 - 113°F)	40 - 45°C (104 - 113°F)	39 - 42°C (102 - 108°F)
Skin Temperature Monitoring	Integrated thermometer + patient's feedback (BTL-785-1, 2, 3)	Integrated thermometer + patient's feedback (BTL-785-1, 2, 3)	Integrated thermometer + Skin temperature measurement
Ultrasonic Tip Pre-heating Function	Yes (BTL-785-1, 2)	Yes (BTL-785-1, 2)	No

Massage Attachment	Yes (BTL-785-1)	Yes (BTL-785-1)	Yes
Number of Microneedles	6 x 6	6 x 6	N/A
Handsfree applicator	Yes	Yes	N/A
Depth of Microneedle Electrodes	0.5 – 4 mm	0.5 – 4 mm	N/A
Number of Pins of Superficial Tips	32	32	N/A
	64	64	N/A
Sterilization Method	Ethylene oxide	Ethylene oxide	N/A
Neutral Electrode Area	169 cm^2	169 cm^2	118 cm^2
System Weight	65 kg (143 lb)	60 kg (132 lb)	15.3 kg (33.7 lb)
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")	230 x 390 x 260 mm (9.06" x 15.35" x 10.24")

New Indication for Use for Applicator BTL-785-7

The BTL-785X and its hands-free applicator BTL-785-7 are newly intended for non-invasive temporary reduction of facial wrinkles. This indication is supported by comparison with the primary and secondary predicate device and data from the clinical investigation. The new indication is proposed based on the

clinical trial's positive feedback from the participants, as well as the results achieved in the study. Additionally, the safety of the device has been evaluated during the clinical investigation and no new risks have been identified.

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

Substantial Equivalence

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

Therefore, the BTL-785X device is substantially equivalent to the predicate devices.

Conclusion

Based upon the intended use, comparison of technical characteristics and performance testing provided in this premarket notification, the BTL-785X device has been shown to be substantially equivalent to the currently cleared predicate device and secondary predicate device for requested intended use.