March 28, 2024

BTL Industries, Inc.
David Chmel
CEO North America
362 Elm Street
Marlborough, Massachusetts 01752

Re: K233604
Trade/Device Name: Btl-785s
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, PBX
Dated: February 27, 2024
Received: February 27, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2024.03.28 11:09:32 -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)*
K233604

Device Name
BTL-785S

Indications for Use *(Describe)*
The BTL-785S device has the following indications for use:

The BTL-785S 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-785S 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-785S 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-785S 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-785S 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-785S with BTL-785-7 Handpiece used with hands-free applicators:
BTL-785-7-1 & BTL-785-7-7, BTL-785-7-2 & BTL-785-7-8 single-use applicators are 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.

BTL-785-7-1 & BTL-785-7-2 single-use applicators are intended to provide:
- Non-invasive temporary reduction of facial wrinkles.

BTL-785-7-9 single-use applicator is intended to:
- Affect the appearance of lax tissue in the submental area.

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."

BTL Industries

510(k) Summary

K233604

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 27, 2024

Device

Trade/Proprietary Name:	BTL-785S
Primary Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Regulation:	21 CFR 878.4400, Class II
Classification Product Code:	GEI, PBX

BTL Industries

Legally Marketed Predicate Device

The BTL-785S 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-785X
Original 510(k) Sponsor: BTL Industries Inc.
510(k) Number: K222556

Reference device:
SculpSure
Original 510(k) Sponsor: Cynosure
510(k) Number: K182741

Product Description

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

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

- microprocessor-driven control unit
- radiofrequency generator
- user interface with 15.6" color touch screen
- applicators
- exchangeable applicator tips

Technological characteristics

The BTL-785S device has identical technological characteristics compared to its primary predicate device. The BTL-785S 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 Industries

- 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 applicators 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 face and small and sensitive areas. The therapy is provided with single use electrodes only.

BTL Industries

Indications for Use

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

The BTL-785S 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-785S 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-785S 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-785S 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-785S 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, the use of the BTL-785-4 applicator is limited to Skin Types I-IV.

The BTL-785S with BTL-785-7 Handpiece used with hands-free applicators:

BTL-785-7-1 & BTL-785-7-7, BTL-785-7-2 & BTL-785-7-8 single-use applicators are 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.

BTL-785-7-1 & BTL-785-7-2 single-use applicators are intended to provide:

- Non-invasive temporary reduction of facial wrinkles.

BTL-785-7-9 single-use applicator is intended to:

-
- Affect the appearance of lax tissue in the submental area.

BTL Industries

Performance Data

The BTL-785S 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 Industries

BTL-785S with BTL-785-7 handpiece and BTL-785-7-9 single-use applicator clinical performance data

A clinical study was conducted to demonstrate the performance, clinical efficacy and safety of the BTL-785-7-9 non-invasive single-use applicator for its effect on the appearance of lax tissue in the submental area. 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-785-7-9 non-invasive single-use applicator.

In total, N=56 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 analysis of baseline and 3-month photography data indicates clinically favorable cosmetic results achieving the secondary endpoints:

A score improvement of at least 1.0 grade point in at least 75% of treated subjects. GAIS evaluation by three independent reviewers showed that a score of at least 1 point on the scale (referring to improved appearance) was documented in 51 of 56 subjects (91%).

Evaluation of effect on appereance of lax skin in submental area. At 3 months, 46 subjects (82%) exhibited a ≥ 20 mm^2 reduction in the submental area. The tissue lift and the response rate yielded consistent results for both the right and left side of the face. Furthermore, of those 46 subjects with tissue lift ≥ 20 mm^2, 43 (93%) were identified by the independent reviewers by using GAIS as having visible improvement in the treated area at 3 months.

The overall satisfaction with the study treatment outcome and therapy comfort. At 3 months, the vast majority of subjects reported their satisfaction with the therapy outcomes as 56 (100%) subjects answered “satisfied” or “very satisfied” to the question “Overall how are you satisfied with the therapy?”. The 56 subjects (100%) answered “satisfied or “very satisfied” to the question “Overall how satisfied are you with the chin-toning after the therapy” and 55 subjects (98%) answered “satisfied” of “very satisfied” to the question “Overall how satisfied are you with the skin laxity of the treated area after the therapy”. In total 54 subjects (96%) “agreed” or “strongly agreed” with the statement “I found the treatment comfortable”.

Pain sensation assessed by 10-point analogue scale yielded an average score of 0.46 ± 0.81 points. Scores of 55 (98%) subjects fell into the none to mild pain range (0-3).

Based on 3-month follow-ups, the treatment with the BTL-785S device equipped with BTL-785-7 handpiece and BTL-785-7-9 single-use applicator has shown to be both safe and effective for its effect on the appearance of lax tissue in the submental area with high satisfaction levels.

BTL Industries

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

Study design	Single-center single-arm, open-label, interventional design
Sample size	56 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
Secondary endpoints	To evaluate the safety of the BTL-785F device with the BTL-785-7-9 applicator To evaluate the effect on submental skin laxity. To assess the participants' satisfaction from the therapy outcome. To assess how comfortable the therapy is.
Secondary endpoint results	GAIS evaluation by three independent reviewers showed that a score of at least 1 point on the scale (referring to improved appearance) was documented in 51 of 56 subjects (91%). At 3 months, 46 subjects (82%) exhibited a ≥ 20 mm^2 reduction in the submental area. In addition 43 (93%) of responders were identified by the independent reviewers by using GAIS as having visible improvement in the treated area at 3 months. At 3 months, the vast majority of subjects reported their satisfaction with the therapy outcomes and found the treatment comfortable (fell into the none to moderate pain)

BTL Industries

Comparison with the Predicate Device

510(k) number	**Not assigned**	**K222556**	**K182741**
Device name	BTL-785S	BTL-785X	SculpSure
Company name	BTL Industries, Inc.	BTL Industries, Inc.	Cynosure
Type	Subject device	Primary predicate	Reference device
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 878.5400 PKT – Laser for disruption of adipocyte cells for aesthetic use
Indications for Use	The BTL-785S device has the following indications for use: The BTL-785S 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-785S with BTL-785-2 applicator is indicated to provide heating for the	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	The Cynosure SculpSure™ is intended for non-invasive lipolysis of the abdomen, flanks, back, and thighs in individuals with a Body Mass Index (BMI) of 30 or less. In addition, the device is intended for non-invasive lipolysis of the submental area in individuals with a BMI of 49 or less. The device is intended to affect the appearance of visible fat bulges in the abdomen, flanks, back, thighs and submental area. When using the petite mask for non-invasive lipolysis of the submental area, the device can also affect the

BTL Industries

	purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The BTL-785S 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-785S 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-785S 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, the use of the BTL-785-4 applicator is limited to Skin Types I-IV.	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. 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	appearance of lax tissue in the submental area.

	The BTL-785S with BTL-785-7 handpiece used with hands-free applicators: BTL-785-7-1 & BTL-785-7-7, BTL-785-7-2 & BTL-785-7-8 single-use applicators are 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. BTL-785-7-1 & BTL-785-7-2 single-use applicators are intended to provide: • Non-invasive temporary reduction of facial wrinkles. BTL-785-7-9 single-use applicator is intended to: • Affect the appearance of lax tissue in the submental area.	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.	
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	Application of the heat to the tissue via RF energy. Massaging of body parts with massage attachment. (785-1 applicator only). Radiofrequency accompanied by	Application of the heat to the tissue via Laser energy.

	electromagnetic stimulation (785-7 applicator only).	electromagnetic stimulation (785-7 applicator only).	
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	200-240V~, Single Phase
Type of Energy Applied	Electromagnetic Energy – Radiofrequency	Electromagnetic Energy – Radiofrequency	Laser energy – Diode Laser
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)	N/A
Mode of Operation	Monopolar	Monopolar	N/A
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)	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)	N/A

	25 W (BTL-785-4-4, 8) 20 W (BTL-785-4-3, 7) 42.5 W (BTL-785-7)	25 W (BTL-785-4-4, 8) 20 W (BTL-785-4-3, 7) 39.8 W (BTL-785-7)	
Effective Treatment Temperature (BTL-785-1, BTL-785-2, BTL-785-3, BTL-785-7)	40 - 45°C (104 - 113°F)	40 - 45°C (104 - 113°F)	Up to 47°C
Skin Temperature Monitoring	Integrated thermometer + patient's feedback (BTL-785-1, 2, 3 – integrated thermometer)	Integrated thermometer + patient's feedback (BTL-785-1, 2, 3)	N/A
Ultrasonic Tip Pre-heating Function	Yes (BTL-785-1, 2)	Yes (BTL-785-1, 2)	N/A
Massage Attachment	Yes (BTL-785-1)	Yes (BTL-785-1)	N/A
Number of Microneedles	6 x 6	6 x 6	N/A
Handsfree applicator	Yes	Yes	Yes
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

BTL Industries

Neutral Electrode Area	169 cm^2	169 cm^2	N/A
System Weight	65 kg (143 lb)	65 kg (143 lb)	Not known
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")	Not known

New Indication for Use for BTL-785-7 and its applicator BTL-785-7-9

The BTL-785S with BTL-785-7 handpiece and its single-use applicators has new indication for use to affect the appearance of lax skin in submental area.

The new indication for BTL-785-7 and its BTL-785-7-9 applicator:

- Affect the appearance of lax tissue in the submental area.

is supported by a clinical data from clinical trial involving 56 subjects, who have been treated and completed 3-month follow-up. The new indication is proposed based on the 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. The difference does not raise any new questions of safety or effectiveness.

Substantial Equivalence

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

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

Conclusion

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