March 17, 2026

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

Re: K253750
Trade/Device Name: Btl-785neh
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 20, 2026
Received: February 20, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.03.17 17:56:37 -04'00'

Colin Kejing Chen, Ph.D.
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253750

Please provide the device trade name(s).

BTL-785NEH

Please provide your Indications for Use below.

The BTL-785NEH device has the following indications for use:
The BTL-785NEH 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-785NEH with BTL-785-2 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-785NEH 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-785NEH with BTL-785-4 applicator used with tips BTL-785-4-5 and BTL-785-4-6 is intended for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.
The BTL-785NEH with BTL-785-4 applicator used with tips BTL-785-4-3 and BTL-785-4-4 is intended for dermatological procedures requiring fractional treatment of the skin.
At higher energy levels greater than 62 mJ/pin or microneedle, the use of the BTL-785-4 applicator is limited to Skin Types I-IV.
The BTL-785NEH 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, BTL-785-7-10, BTL-785-7-11 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

BTL Industries

510(k) Summary

K253750

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: 20 February 2026

Device

Trade/Proprietary Name:	BTL-785NEH
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-785NEH is a state-of-the-art radiofrequency 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:

Device name: BTL-785S
Original 510(k) Sponsor: BTL Industries Inc.
510(k) Number: K233604

Product Description

The BTL-785NEH is a state-of-the-art radiofrequency, ultrasound and electrostimulation platform. The device is comprised of a control unit and applicators. The control unit of the system is equipped with a large color touch screen that facilitates the use of the device. The on-screen information guides the user step-by-step through the entire therapy procedure. 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 handpiece with 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, neck and small and sensitive areas. The therapy is provided with single use electrodes only.

Clinical Performance Data

Not applicable

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Indications for Use

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

The BTL-785NEH 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-785NEH with BTL-785-2 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-785NEH 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-785NEH with BTL-785-4 applicator used with tips BTL-785-4-5 and BTL-785-4-6 is intended for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

The BTL-785NEH with BTL-785-4 applicator used with tips BTL-785-4-3 and BTL-785-4-4 is intended for dermatological procedures requiring fractional treatment of the skin.

At higher energy levels greater than 62 mJ/pin or microneedle, the use of the BTL-785-4 applicator is limited to Skin Types I-IV.

The BTL-785NEH 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**,** BTL-785-7-10, BTL-785-7-11 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.

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Performance Data

The BTL-785NEH 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

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Comparison with the Predicate Device

510(k) number	K253750	K233604
Device name	BTL-785NEH	BTL-785S
Company name	BTL Industries, Inc.	BTL Industries, Inc.
Type	Subject device	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
Indications for Use	The BTL-785NEH device has the following indications for use: The BTL-785NEH 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-785NEH with BTL-785-2 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-785NEH with BTL-785-3 applicator is intended to provide	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

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	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-785NEH with BTL-785-4 applicator used with tips BTL-785-4-5 and BTL-785-4-6 is intended for use in dermatological and general surgical procedures for electrocoagulation and hemostasis. The BTL-785NEH with BTL-785-4 applicator used with tips BTL-785-4-3 and BTL-785-4-4 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-785NEH 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, BTL-785-7-10, BTL-785-7-11 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.	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, 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.

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	BTL-785-7-9 single-use applicator is intended to: • Affect the appearance of lax tissue in the submental area. BTL-785-7-11 single-use applicator is intended to: • Affect the appearance of lax tissue (eye bags) in the periorbital area.	BTL-785-7-9 single-use applicator is intended to: • Affect the appearance of lax tissue in the submental area.
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 applicators only).	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 applicators only).
Clinical 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
Type of Energy Applied	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)
Mode of Operation	Monopolar	Monopolar
User Interface	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-785-4-5, 6) 25 W (BTL-785-4-4) 15 W (BTL-785-4-3) 57 W (BTL-785-7)	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) 42.5 W (BTL-785-7)

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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)
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 – integrated thermometer)
Ultrasonic Tip Pre-heating Function	Yes (BTL-785-1, 2)	Yes (BTL-785-1, 2)
Massage Attachment	Yes (BTL-785-1)	Yes (BTL-785-1)
Number of Microneedles	6 x 6	6 x 6
Handsfree applicator	Yes	Yes
Depth of Microneedle Electrodes	0.5 – 4 mm	0.5 – 4 mm
Number of Pins of Superficial Tips	32	32
	64	64
Sterilization Method	Ethylene oxide	Ethylene oxide
Neutral Electrode Area	169 cm^2	169 cm^2
System Weight	65 kg (143 lb)	65 kg (143 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")

Substantial Equivalence

The BTL-785NEH device has the same technological characteristics, mode of action and comparable intended use to the predicate device. Any differences between the predicate device and BTL-785NEH device have no significant influence on safety or effectiveness of the BTL-785NEH device. Therefore, the BTL-785NEH 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-785NEH device has been shown to be substantially equivalent to the currently cleared predicate device and secondary predicate device for requested intended use.