December 13, 2024

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

Re: K242532
Trade/Device Name: BTL-785BNF-E
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: November 20, 2024
Received: November 20, 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.

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
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Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242532

Device Name

BTL-785BNF-E

Indications for Use *(Describe)*

The BTL-785BNF-E device has the following indications for use:
The device is indicated for aesthetic use including facial and neck or body skin stimulation.

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.

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510(k) Summary
K242532

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:	November 20, 2024

Device

Trade/Proprietary Name:	BTL-785BNF-E
Primary Classification Name:	Transcutaneous Electrical Nerve Stimulator for Pain Relief
Classification Regulation:	21 CFR 882.5890, Class II
Classification Product Code:	NFO

Legally Marketed Predicate Device

The BTL-785BNF-E is a state-of-the-art device with accessories intended for electrostimulation therapy and RF warming, and is substantially equivalent to the following product that is already cleared for distribution in the USA under the following 510(k) Premarket Notification number:

- BTL-785BNF Handpiece (K233604)

Product Description

The BTL-785BNF-E is a state-of-the-art electrostimulation device that enables the application of therapy by electrical stimulation to patient's skin for aesthetic use.

The main control unit 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 therapeutic parameters are set using the touch screen of the device. During the therapy, the device displays information about the applied therapy type, the remaining therapy time and the main therapy parameters on the screen.

The generated electrical stimulation is intended to interact with the tissues of the human body in order to achieve skin stimulation in the face.

The device consists of the following main components:

- BTL-785 main unit
- BTL-785-7 Handpiece
- Single-use application electrodes
- Holding arm
- Connection cables
- Therapy discomfort button

Indications for Use

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

The device is indicated for aesthetic use including facial and neck or body skin stimulation.

Non-clinical Testing (Performance Data)

The BTL-785BNF-E 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 60601-2-10	Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
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 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

Clinical performance data

A clinical study was not conducted.

Comparison with the Predicate Device

510(k) number	**Not assigned**	**K232172**
Device name	BTL-785BNF-E	BTL-785BNF Handpiece
Company name	BTL Industries, Inc.	BTL Industries, Inc.
Type	Subject device	Predicate device
Product Code and Regulation	Neurology 21 CFR 882.5890 NFO – Stimulator, Transcutaneous Electrical, Aesthetic Purposes	Neurology 21 CFR 882.5890 NFO – Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Clinical use	Rx Only	Rx Only
Indications for Use	The device is indicated for aesthetic use including facial and neck or body skin stimulation.	The device is indicated for aesthetic use including facial and neck or body skin stimulation.
Anatomic Sites	Face, neck, and body	Face, neck, and body
Compliance with Voluntary Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 ISO 14971 IEC 62366	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 ISO 14971 IEC 62366
Handpiece Weight	2500 g	2500 g
Handpiece Dimensions [W x H x D]	38.98” x 53.94” x 34.65”	38.98” x 53.94” x 34.65”
Housing Materials and Construction	PCBs and leads inside plastic, or foam case housing	PCBs and leads inside plastic, or foam case housing
User Interface Display	Yes on the main controll unit.	Yes on the main controll unit.
Energy type	Electric stimulation	Electric stimulation
Power source	Mains power 100-240V, 50-60 Hz	Mains power 100-240V, 50-60 Hz
Waveform Shape	Biphasic rectangular pulse modulated by trapezoidal	Biphasic rectangular pulse modulated by trapezoidal

Max output voltage [V] (+/-20%) **- at 500 Ω** **- at 2,000 Ω** **- at 10,000 Ω**	**BTL-785-7-2, -8, -9** 48,5V @ 500 Ω 48,5V @ 2000 Ω 0 @ 10 000 Ω **BTL-785-7-1, -7** 48,5V @ 500 Ω 48,5V @ 2000 Ω 0 @ 10 000 Ω **BTL-785-7-11** 48,5V @ 500 Ω 48,5V @ 2000 Ω 0 @ 10 000 Ω	**BTL-785-7-2, -8, -9** 48,5V @ 500 Ω 48,5V @ 2000 Ω 0 @ 10 000 Ω **BTL-785-7-1, -7** 48,5V @ 500 Ω 48,5V @ 2000 Ω 0 @ 10 000 Ω
Max output current **(+/-20%)** **- at 500 Ω** **- at 2,000 Ω** **- at 10,000 Ω**	**BTL-785-7-2, -8, -9** Max. 130 mA @ 10 - 373 Ohm 97 mA @ 500 Ω 24 mA @ 2000 Ω 0 mA @ 10000 Ω **BTL-785-7-1, -7** Max. 64 mA @ 10 - 757 Ω 64 mA @ 500 Ω 24 mA @ 2000 Ω 0 mA @ 10000 Ω **BTL-785-7-11** Max. 30 mA @ 10 - 1900 Ω 30 mA @ 500 Ω 26 mA @ 2000 Ω 0 mA @ 10000 Ω	**BTL-785-7-2, -8, -9** Max. 130 mA @ 10 - 373 Ohm 97 mA @ 500 Ω 24 mA @ 2000 Ω 0 mA @ 10000 Ω **BTL-785-7-1, -7** Max. 64 mA @ 10 - 757 Ω 64 mA @ 500 Ω 24 mA @ 2000 Ω 0 mA @ 10000 Ω

Max current density at 500 Ω [µA/mm^2]	BTL-785-7-2 – 243 µA/mm^2 BTL-785-7-8 - 335 µA/mm^2 BTL-785-7-9 - 277 µA/mm^2 BTL-785-7-1 – 168 µA/mm^2 BTL-785-7-7 - 337 µA/mm^2 BTL-785-7-11 – 164 µA/mm^2	BTL-785-7-2 – 243 µA/mm^2 BTL-785-7-8 - 335 µA/mm^2 BTL-785-7-9 - 277 µA/mm^2 BTL-785-7-1 – 168 µA/mm^2 BTL-785-7-7 - 337 µA/mm^2
Max average power density at 500 Ω [W/cm^2]	BTL-785-7-2 – 0,047 W/cm^2 BTL-785-7-8 - 0,065 W/cm^2 BTL-785-7-9 - 0,054 W/cm^2 BTL-785-7-1 – 0,033 W/cm^2 BTL-785-7-7 - 0,065 W/cm^2 BTL-785-7-11 – 0,032 W/cm^2	BTL-785-7-2 – 0,047 W/cm^2 BTL-785-7-8 - 0,065 W/cm^2 BTL-785-7-9 - 0,054 W/cm^2 BTL-785-7-1 – 0,033 W/cm^2 BTL-785-7-7 - 0,065 W/cm^2
Net Charge per pulse	Zero (pulse is biphasic symmetrical)	Zero (pulse is biphasic symmetrical)
Max phase charge per pulse at 500 Ω [µC]	**BTL-785-7-2, -8, -9** 15 µC **BTL-785-7-1, -7** 10 µC **BTL-785-7-11** 5 µC	**BTL-785-7-2, -8, -9** 15 µC **BTL-785-7-1, -7** 10 µC
Duration of primary [µs] (depolarizing phase)	80 µs	80 µs
Pulse Duration [µs]	160 µs	160 µs
Frequency [Hz]	250	250

(a) Electrodes materials	Conductive ink (Silver)	Conductive ink (Silver)
(b) electroconductive media	Conductive hydrogel	Conductive hydrogel
(c) electrode-to-skin impedance range	10-5000 Ohm	10-5000 Ohm
(d) max duration of use	20 min	20 min
(e) conductive surface area	BTL-785-7-1 - 3.8 cm^2 BTL-785-7-2 - 4 cm^2 BTL-785-7-7 - 1.9 cm^2 BTL-785-7-8 - 2.9 cm^2 BTL-785-7-9 - 3.5 cm^2 BTL-785-7-11 – 1.8 cm^2	BTL-785-7-1 - 3.8 cm^2 BTL-785-7-2 - 4 cm^2 BTL-785-7-7 - 1.9 cm^2 BTL-785-7-8 - 2.9 cm^2 BTL-785-7-9 - 3.5 cm^2

Substantial Equivalence

The difference between the subject device and the predicate device (K232172) is the introduction of a new disposable applicator, the BTL-785-7-11. This applicator features a shape specifically designed to better fit the treatment area - the upper cheek and the periocular region outside the orbital rim. Otherwise, it remains substantially equivalent to the applicators previously cleared for the predicate device (K232172) in terms of materials used, manufacturing processes, technology used, method of use, and intended purpose.

The BTL-785BNF-E device has the same technological characteristics and intended use compared to the predicate device. Differences between the predicate device and the BTL-785BNF-E have no significant influence on safety or effectiveness of the BTL-785BNF-E device.

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