May 9, 2025

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

Re: K243290
Trade/Device Name: BTL-785MJ
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NUW, NFO
Dated: October 18, 2024
Received: April 10, 2025

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
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Enclosure

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)*

K243290

Device Name

BTL-785MJ

Indications for Use *(Describe)*

The BTL-785MJ device with the controller and single-use applicators has the following indications for use:
1. To relieve symptoms associated with muscle spasm, to treat temporomandibular joint (TMJ) dysfunction and associated pain
2. Muscle re-education
3. Increasing blood flow
4. Maintain or increase mandibular range of motion

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.

510(k) Summary – K243290

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:	May 08, 2025

Device

Trade/Proprietary Name:	BTL-785MJ
Common Name:	Stimulator, muscle, powered, dental
Primary Classification Name:	Powered muscle stimulator
Classification Regulation:	21 CFR 890.5850, Class II
Primary Product Code:	NUW
Secondary Product Code:	NFO

Legally Marketed Predicate Device

The BTL-785MJ is substantially equivalent to the following product(s) that are already cleared for distribution in the USA under the following 510(k) Premarket Notification numbers:

Primary predicate:

Device name: D function
Original 510(k) Sponsor: ITO CO., LTD.
510(k) Number: K203525

Reference device:

Device name: BTL-785BNF-E
Original 510(k) Sponsor: BTL Industries, Inc.
510(k) Number: K242532

Product Description

The BTL-785MJ is a state-of-the-art electrostimulation and radiofrequency platform with accessories that enables the application of therapy by electrical stimulation.

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 therapeutic parameters are 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.

The generated electromagnetic field is intended to interact with the tissues of the human body in order to relieve symptoms associated with muscle spasm, to treat temporomandibular joint (TMJ) dysfunction and associated pain, muscle re-education, increase blood flow and maintain or increase mandibular range of motion.

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

- Main unit
- Handpiece
- Holding arm
- Connection cables
- Single-use applicators
- Therapy discomfort button

Indications for Use

The BTL-785MJ device with the controller and single-use applicators has the following indications for use:

1. To relieve symptoms associated with muscle spasm, to treat temporomandibular joint (TMJ) dysfunction and associated pain
2. Muscle re-education
3. Increasing blood flow
4. Maintain or increase mandibular range of motion

Non-clinical Testing (Performance Data)

The BTL-785MJ 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 **Device name** **Company name:**	**K243290** BTL-785MJ BTL Industries, Inc.	**K203525** D function ITO CO., LTD.	**K242532** BTL-785BNF-E BTL Industries, Inc.
Type	Subject device	Predicate device	Reference device
Product Code and Regulation	Physical medicine Dental 21 CFR 890.5850 NUW – Stimulator, Muscle, Powered, Dental	Physical medicine Dental 21 CFR 890.5850 NUW – Stimulator, Muscle, Powered, Dental	Neurology Neurology 21 CFR 882.5890 NFO – Stimulator, Transcutaneous Electrical, Aesthetic Purposes
Indications for Use	The BTL-785MJ device with the controller and single-use applicators has the following indications for use: 1. To relieve symptoms associated with muscle spasm, to treat temporomandibular joint (TMJ) dysfunction and associated pain 2. Muscle re-education 3. Increasing blood flow 4. Maintain or increase mandibular range of motion	1) To relieve symptoms associated with muscle spasm, to treat temporomandibular joint (TMJ) dysfunction and associated pain 2) Muscle re-education 3) Increasing blood flow 4) Maintain or increase mandibular range of motion	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.
Principle of Action	Electrostimulation	Electrostimulation	Electrostimulation
Clinical Use	Prescription use	Prescription use	Prescription use

Energy Source	100 – 120 V AC, 50/60 Hz 200 – 240 V AC, 50/60 Hz	AC 100-240V, 50/60Hz DC 12 V (AC adaptor) DC 7.4 (Lithium ion battery)	100 – 120 V AC, 50/60 Hz 200 – 240 V AC, 50/60 Hz
Electrical Safety & EMC Testing	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	ANSI AAMI 60601-1 IEC 60601-1-2 IEC 60601-2-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10
Energy Type	Electric stimulation	Electric stimulation	Electric stimulation
Accessory Attachment Method	Pad – single-use applicator	Pad – single-use applicator	Pad – single-use applicator
Therapy time	20-60 minutes	60 minutes (Up to 480 min)	20 minutes
Pulse Width	Preset 1: Up to 150 µs Preset 2: 488 µs	PAIN: Up to 150µs CARE: 488 µs MCR: 150ms	160 µs
Output Frequency (Hz)	Preset 1: Up to 200 Preset 2: 0.67	PAIN: Up to 200 CARE: 0.67 MCR: 400	250
Output Current	Preset 1 : Up to 80 mA Preset 2: Up to 80 mA	PAIN: Up to 80 mA CARE: 24 mA MCR: 750 µA	Up to 130 mA
Max. Output Voltage [V]	BTL-785-7-2, -8 48,5V @ 500 Ω 48,5V @ 2000 Ω 0 @ 10 000 Ω	Not publicly available	BTL-785-7-2, -8 48,5V @ 500 Ω 48,5V @ 2000 Ω 0 @ 10 000 Ω
Max. Current density at 500 Ω [µA/mm²]	BTL-785-7-2 – 200 µA/mm² BTL-785-7-8 -276 µA/mm²	Not publicly available	BTL-785-7-2 – 243 µA/mm² BTL-785-7-8 - 335 µA/mm²
Max average power density at 500 Ω [W/cm²]	BTL-785-7-2 – 0,058 W/cm² BTL-785-7-8 -0.082 W/cm²	Not publicly available	BTL-785-7-2 – 0,047 W/cm² BTL-785-7-8 - 0,065 W/cm²
Pulse Shape	Rectangular	Rectangular	Rectangular
Channel Numbers	2	2	Up to 3

Electrical Safety Class	Class II, BF	Class II, BF	Class II, BF
Timer	Yes	Yes	Yes
Buzzer	Yes	Yes	Yes
Display	Yes	Yes	Yes
(a) Electrodes materials **(b) Electrocon-ductive media** **(c) electrode-to-skin impedance range** **(d) conductive surface area**	a) Conductive ink (Silver) b) Conductive hydrogel c) 10-5000 Ohm d) BTL-785-7-2 - 4 cm2 BTL-785-7-8 - 2.9 cm2	a) Not publicly available b) Not publicly available c) Not publicly available d) Not publicly available	a) Conductive ink (Silver) b) Conductive hydrogel c) 10-5000 Ohm d) BTL-785-7-2 - 4 cm2 BTL-785-7-8 - 2.9 cm2
System Weight	65 kg (143 lb)	230 g (0.5 lb)	65 kg (143 lb)
System Dimensions (W×H×D)	53.94" x 26.38" x 26.38"	3.3" x 0.93" x 5.9"	53.94" x 26.38" x 26.38"

Substantial Equivalence

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

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