September 18, 2023

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

Re: K232172
Trade/Device Name: BTL-785BNF Handpiece
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NFO
Dated: July 3, 2023
Received: July 21, 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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232172

Device Name
BTL-785BNF Handpiece

Indications for Use *(Describe)*

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

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

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510(k) Summary

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:	June 23, 2023

Device

Trade/Proprietary Name:	BTL-785BNF Handpiece
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 Handpiece is a state-of-the-art device with accessories intended for electrostimulation therapy, 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:

- Avazzia OTC TENS for Aesthetics, model BEST-AV1: EZZI-LIFT Device (K191951)

Product Description

The BTL-785BNF Handpiece is a state-of-the-art electrostimulation device that enables the application of therapy by an electromagnetic field.

The subjected device is intended to be used together with a main control unit that 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.

The BTL-785BNF Handpiece is a specially developed device that can be used with the applicators and the main control unit. The generated electromagnetic field is intended to interact with the tissues of the human body in order to achieve neuro-muscle stimulation. The radiofrequency is providing a low degree of warming to enhance the patient's comfort during the treatment.

The BTL-785BNF Handpiece consists of the following main components:

- BTL-785BNF Handpiece
- Single-use application electrodes
- Holding arm
- Connection cables
- Therapy discomfort button

Indications for Use

The BTL-785BNF Handpiece 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 Handpiece 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**	**K232172** BTL-785BNF Handpiece BTL Industries, Inc.	**K191951** Avazzia OTC TENS for Aesthetics, model BEST-AV1: EZZI-LIFT Device Avazzia, 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

Indications for Use	The device is indicated for aesthetic use including facial and neck or body skin stimulation.	Device is indicated for over-the counter aesthetic use including facial and neck stimulation or body skin stimulation.
Anatomic Sites	Face, neck, and body	Face, neck, and body
Number of Output Modes	1	4
Low Battery Indicator	N/A	Yes
Automatic shut off	N/A	60 min
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
Compliance with 21 CFR 898	Yes	Yes
Weight	2500 g	150 g
Dimensions [W x H x D] inches	38.98” x 53.94” x 34.65”	2.6" X 4.7" X 1.35"
Housing Materials and Construction	PCBs and leads inside plastic, or foam case housing	PCBs inside plastic case housing
User Interface Display	Yes on the main controll unit.	LEDs and switches
Energy type	Electric stimulation	Electric stimulation
Additional energy	RF warming	N/A
Number, Size, and Type of Batteries	Mains power 100-240V, 50-60 Hz	Two 1.5 V AA batteries
Waveform Shape	Biphasic rectangular pulse modulated by trapezoidal	positive square wave followed by a damped sinusoidal waveform of variable duration depending on damping and body loading
Max output voltage [V] (+/-20%) **- at 500 Ω** **- at 2,000 Ω** **- at 10,000 Ω**	BTL-785-2, -8, -9 Max. 48,5V @ 10 - 373 Ω 48,5V @ 500 Ω 48,5V @ 2000 Ω 0 @ 10 000 Ω	-42 @ 500 Ω -122 @ 2000 Ω -348 @ 10 000 Ω

	BTL-785-1, -7 Max. 48,5V @ 10 - 757 Ω 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-785-2, -8, -9 Max. 130 mA @ 10 - 373 Ohm 97 mA @ 500 Ω 24 mA @ 2000 Ω 0 mA @ 10000 Ω BTL-785-1, -7 Max. 64 mA @ 10 - 757 Ω 64 mA @ 500 Ω 24 mA @ 2000 Ω 0 mA @ 10000 Ω	Max. 500 µA 363 µA @ 500 Ω 117 µA @ 2000 Ω 38 µA @ 10000 Ω
Max current density at 500 Ω [µA/mm^2]	BTL-785-2 - 243 µA/mm^2 BTL-785-8 - 335 µA/mm^2 BTL-785-9 - 277 µA/mm^2 BTL-785-1 – 168 µA/mm^2 BTL-785-7 - 337 µA/mm^2	Built-in, Y, Brush: 800 µA/mm^2 Pencil: 19,000 µA/mm^2
Max average power density at 500 Ω [µW/mm^2]	BTL-785-2 – 0,047 W/cm^2 BTL-785-8 - 0,065 W/cm^2 BTL-785-9 - 0,054 W/cm^2 BTL-785-1 – 0,033 W/cm^2 BTL-785-7 - 0,065 W/cm^2	Built-in, Y, Brush: 500 µW/mm^2 Pencil: 3,500 µW/mm^2
Net Charge per pulse	Zero (pulse is biphasic symmetrical)	4 µC
Max phase charge per pulse at 500 Ω [µC]	BTL-785-2, -8, -9 15 µC BTL-785-1, -7 10 µC	10 µC
Duration of primary [µs] (depolarizing phase)	80 µs	500 µs
Pulse Duration [µs]	160 µs	1 100 µs
Frequency [Hz]	250	15 to 121
Electrodes **(a) materials** **(b) electroconductive media** **(c) electrode-to-skin impedance range**	Conductive ink (Silver) Conductive hydrogel 10-5000 Ohm	Stainless steel 316 n/a less than 15

(d) max duration of use (same as device shut off)	20 min	60 min
(e) conductive surface area	BTL-785-1 - 3.8 cm^2 BTL-785-2 - 4 cm^2 BTL-785-7 - 1.9 cm^2 BTL-785-8 - 2.9 cm^2 BTL-785-9 - 3.5 cm^2	built in rectangular - 1.94 cm^2 spherical - 5.60 cm^2 brush/comb - 0.56 cm^2 small circular, pencil-like - 0.023 cm^2

Substantial Equivalence

The BTL-785BNF Handpiece device has equivalent technological characteristics and similar intended use compared to the predicate device.

The predicate device utilizes electric stimulation in order to achieve therapeutic effect. The subjected device BTL-785BNF Handpiece also utilizes electromagnetic stimulation for its main therapeutic effect; however, the device is also equipped with a monopolar radiofrequency generator. The RF warms the patient at the application site to increase patient convenience during therapy.

Any differences between the predicate devices and BTL-785BNF Handpiece have no significant influence on safety or effectiveness of the BTL-785BNF Handpiece.

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