January 30, 2025

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

Re: K241270
Trade/Device Name: Btl-754
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX, ONG
Dated: December 26, 2024
Received: December 26, 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,

YAN FU -S Digitally signed by YAN FU -S
Date: 2025.01.30 09:00:31 -05'00'

for Tanisha Hithe
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)*
K241270

Device Name
BTL-754

Indications for Use *(Describe)*
The BTL-754 device with BTL-754-4 handpiece has the following indications for use:

The 2940nm Fractional handpiece is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, pigmented lesions, and vascular dyschromia.

The 1540nm Fractional handpiece is intended for use in coagulation of soft tissue, skin resurfacing procedures as well as treatment of melasma, striae, acne scars and surgical scars.

The combined 1540nm and 2940nm Fractional handpiece is intended for dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, dyschromia and pigmented lesions.

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.

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"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."

510(k) Summary
K241270

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: 27 January 2025

Device

Trade/Proprietary Name:	BTL-754
Primary Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Regulation:	21 CFR 878.4810, Class II
Classification Product Code:	GEX, ONG

Legally Marketed Predicate Device

The BTL-754 is a state-of-the-art high-frequency energy 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:

Predicate device name: Palomar Icon Aesthetic System
Original 510(k) Sponsor: Cynosure, Inc.
510(k) Number: K142376

Product Description

The BTL-754 is a medical device containing two laser wavelengths. A laser is a device that can generate light in the visible or invisible part of the electromagnetic spectrum. The generation of radiation occurs by means of so-called stimulated emission, thanks to which its beam has specific properties - the laser beam is well directed and can propagate over long distances without much divergence. It can also be focused into a very small spot where a very high intensity is achieved.

The BTL-754 consists of a main unit, articulated mirror arm and applicator. The main unit is equipped with a color touch screen with a wide view angle that makes the device easy to use. The on-screen information informs the operator through the entire therapy procedure. The therapeutic parameters are easily set using the touch screen. During therapy, the screen displays information about therapy parameters. The device is equipped with the Emergency laser stop button for immediate termination of the laser emission.

Technological characteristics

The BTL-754 device has similar technological characteristics compared to its predicate devices.
The BTL-754 device and the predicates are comprised of a system console and applicators.

Indications for Use

The BTL-754 device with BTL-754-4 handpiece has the following indications for use:

The 2940nm Fractional handpiece is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, pigmented lesions, and vascular dyschromia.

The 1540nm Fractional handpiece is intended for use in coagulation of soft tissue, skin resurfacing procedures as well as treatment of melasma, striae, acne scars and surgical scars.

The combined 1540nm and 2940nm Fractional handpiece is intended for dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, dyschromia and pigmented lesions.

Non-clinical Testing (Performance, Bench Testing)

The device has been found to comply with applicable medical device safety standards:

- IEC 60601-1:2020 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2020 - Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests
- IEC 60601-2-22:2019 - Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 - Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-11:2017 - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-23:2021 - Biological evaluation of medical devices - Part 23: Tests for irritation

Sterilization, cleaning and disinfection validation:

- ISO 11737-1:2018+A1:2021 - Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product [Including Amendment 1 (2021)]
- ISO 11737-2:2019 - Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

ISO 17664-1:2021 “Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices

ISO 17665:2024 - Sterilization of health care products – Moist Heat –Requirements for the development, validation and routine control of a sterilization process for medical devices

Basic device performance verified by manufacturer in:

- Measuring of pulse repetition frequency test
- Laser output accuracy test

Clinical Testing

Not applicable to this submission

Comparison with the Predicate Device

510(k) number **Device name** **Company name**	**K241270** **BTL-754** **BTL Industries, Inc.**	**K142376** **Palomar Icon Aesthetic System** **Cynosure, Inc.**
Type	Subject device	Predicate device
Product Code and Regulation	General & Plastic Surgery 21 CFR 878.4810 ONG - Powered Laser Surgical Instrument With Microbeam\Fractional Output GEX - Powered Laser Surgical Instrument	General & Plastic Surgery 21 CFR 878.4810 ONG - Powered Laser Surgical Instrument With Microbeam\Fractional Output GEX - Powered Laser Surgical Instrument

2940nm		
Indications for Use	The 2940nm Fractional handpiece is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, pigmented lesions, and vascular dyschromia.	The 2940 Fractional Ablative Laser Handpiece is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, pigmented lesions, and vascular dyschromia.
Laser media	Er YAG	Er YAG
Wavelength	2940nm	2940nm
Output mode	Pulsed	Pulsed
Pulse width	0.2 – 1.5 ms	0.25, 3, 5 ms
Repetition rate	1-3 Hz	Up to 6 Hz
Application pattern (dots)	10x10 (64mB/cm2)	6x6 (178mB/cm2) 6x6 (469mB/cm2) 10x10 (169mB/cm2)
Microbeam size	250 µm +/-20%	250 µm
Fluence Energy/ microbeam	Up to 24.5mJ/mB	Up to 24mJ/mB

1540nm		
Indications for Use	The 1540nm Fractional handpiece is intended for use in coagulation of soft tissue, skin resurfacing procedures as well as treatment of melasma, striae, acne scars and surgical scars.	The 1540 Fractional Non-ablative Laser Handpiece is intended for use in coagulation of soft tissue, skin resurfacing procedures as well as treatment of melasma, striae, acne scars and surgical scars.
Laser source	Er:Glass	Er:Glass
Wavelength	1540 nm	1540 nm
Output mode	Pulsed	Pulsed
Pulse width	4-7 ms	10, 15 ms
Repetition rate	1-3 Hz	Up to 1.5 Hz
Application pattern (dots)	10x10 (64mB/cm2)	Ø15 (320mB/cm2) Ø15 (115mB/cm2) 12x12 (25mB/cm2)
Microbeam size	300 µm ±30%	Up to 270 µm
Energy/ microbeam	Up to 28mJ/mB	3mJ/mB - 70mJ/mB

1540nm and 2940nm		
Indications for Use	The combined 1540nm and 2940nm Fractional handpiece is intended for dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, dyschromia and pigmented lesions.	The 1540 Fractional Non-ablative Laser and 2940 Fractional Ablative Laser Handpiece combined treatment is intended for dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, dyschromia and pigmented lesions.

Substantial Equivalence

The BTL-754 device has the same intended use as its predicate device. The technological characteristics of the predicate device are comparable to the BTL-754 device. Any differences between the predicate device and BTL-754 have no significant influence on safety and effectiveness of the BTL-754 device. Therefore, the BTL-754 is substantially equivalent to the predicate device.

Conclusion

Based upon the intended use and known technical information provided in this pre-market notification, the BTL-754 device has been shown to be substantially equivalent to currently marketed predicate device K142376.