February 18, 2026

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

Re: K252561
Trade/Device Name: Btl-754ff
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: August 12, 2025
Received: August 13, 2025

Dear Chmel David:

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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2026.02.18 21:42:52 -05'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252561

Device Name
BTL-754FF

Indications for Use *(Describe)*

The BTL-754FF device with
BTL-754-1 handpiece has the following indications for use:
The BTL-754-1 with 2940nm is intended for use in Coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes).
Laser skin resurfacing procedures for the treatment of:
o Acne scars
o Wrinkles
The BTL-754-1 with 1540nm is intended to be used for incision, excision, ablation, and coagulation (hemostasis) of soft tissue. The device is also indicated for the removal of pigmented lesions; photocoagulation of dermatological vascular lesions, including photothermolysis of blood vessels (treatment of facial and leg veins), for the treatment of periorbital and perioral wrinkles, for the treatment of back acne.
The BTL-754-1 with combined 1540nm and 2940nm is intended for dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing, treatment of wrinkles and textural irregularities.

BTL-754-4 handpiece has the following indications for use:
The BTL-754-4 with 2940nm in Fractional mode 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 BTL-754-4 with 1540nm in Fractional mode 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 BTL-754-4 with combined 1540nm and 2940nm in Fractional mode 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 BTL-754-4 with 1540nm in Macro mode is intended for use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue.

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
K252561

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:	18 February 2026

Device

Trade/Proprietary Name:	BTL-754FF
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-754FF 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: BTL-754
510(k) Number: K241270
Original 510(k) Sponsor: BTL Industries, Inc.

Predicate device name: Superbium
510(k) Number: K153229
Original 510(k) Sponsor: BIOS S.R.L

Predicate device name: MCL 31 Dermablate
510(k) Number: K150140
Original 510(k) Sponsor: Asclepion Laser Technologies GMBH

Predicate device name: Aramis II Dermatological Laser
510(k) Number: K023734, K032260
Original 510(k) Sponsor: Quantel Medical

Predicate device name: Alma Harmony
510(k) Number: K233024
Original 510(k) Sponsor: Alma Lasers, Inc.

Product Description

The BTL-754FF is a medical device containing two laser wavelengths. The parameters of each wavelength can be adjusted individually. The device allows the separate application of these wavelengths or their combination. The laser radiation is generated by solid-state lasers and delivered using an articulated arm to an applicator. The laser radiation is applied to the patient's body in a different beam pattern, depending on the applicator used. The absorption of laser radiation in the tissue leads to tissue heating, ablation, or coagulation.

The BTL-754FF consists of a main unit, articulated mirror arm and applicators. 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-754FF device has similar technological characteristics compared to its predicate devices. The BTL-754FF device and the predicates are comprised of a system console and applicators.

Indications for Use

The BTL-754FF device with

BTL-754-1 handpiece has the following indications for use:

- The BTL-754-1 with 2940nm is intended for use in Coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes).
  Laser skin resurfacing procedures for the treatment of:
  - Acne scars
  - Wrinkles
- The BTL-754-1 with 1540nm is intended to be used for incision, excision, ablation, and coagulation (hemostasis) of soft tissue. The device is also indicated for the removal of pigmented lesions; photocoagulation of dermatological vascular lesions, including photothermolysis of blood vessels (treatment of facial and leg veins), for the treatment of periorbital and perioral wrinkles, for the treatment of back acne.
- The BTL-754-1 with combined 1540nm and 2940nm is intended for dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing, treatment of wrinkles and textural irregularities.

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

- The BTL-754-4 with 2940nm in Fractional mode 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 BTL-754-4 with 1540nm in Fractional mode 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 BTL-754-4 with combined 1540nm and 2940nm in Fractional mode 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 BTL-754-4 with 1540nm in Macro mode is intended for use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue.

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

IEC 60825-1:2014 - Safety of laser products - Part 1: Equipment classification and requirements

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 and output parameters were verified independently by manufacturer in:
- Laser beam spot size measurement – test report

Software documentation of the subject device was provided in accordance with the FDA guidance Document - “Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff”, which was issued in 06/14/2023

Clinical Testing

Not applicable to this submission

Comparison with the Predicate Device

510(k) number **Device name** **Company name**	**K252561** **BTL-754FF** **BTL Industries, Inc.**	**K241270** **BTL-754** **BTL Industries, 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
1540nm and 2940nm		
Indications for Use	The BTL-754-4 with combined 1540nm and 2940nm 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 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.

2940nm		
Applicator	BTL-754-4	BTL-754-4
Indications for Use	The BTL-754-4 with 2940nm 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 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.
Laser source	Er:YAG	Er:YAG
Wavelength	2940nm	2940nm
Output mode	Pulsed	Pulsed
Pulse width	0.2 – 1.5 ms	0.2 – 1.5 ms
Repetition rate	1.5-30 Hz	1-3 Hz
Application pattern (dots)	8.8 x 8.8 mm (83mB/cm^2) 64 mB/pulse	10x10 (64mB/cm^2) 64 mB/pulse
Microbeam size	200 µm ±30%	250 µm ±20%
Energy/ microbeam	Up to 22 mJ/mB	Up to 24.5 mJ/mB

1540nm		
Applicator	BTL-754-4	BTL-754-4
Indications for Use	The BTL-754-4 with 1540nm 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 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.
Laser source	Er:Glass	Er:Glass
Wavelength	1540 nm	1540 nm
Output mode	Pulsed	Pulsed
Pulse width	2-8 ms	4-7 ms
Repetition rate	1-4 Hz	1-3 Hz
Application pattern (dots)	8.8 x 8.8 mm (83mB/cm^2) 64 mB/pulse	10x10 (64mB/cm^2) 64 mB/pulse
Microbeam size	250 µm ±30%	300 µm ±30%
Energy/ microbeam	Up to 30.5 mJ/mB	Up to 28 mJ/mB

510(k) number **Device name** **Company name**	**K252561** **BTL-754FF** **BTL Industries, Inc.**	**K233024** **Alma Harmony** **Alma Lasers, Inc.**
Type	Subject device	Predicate device
Product Code and Regulation	General & Plastic Surgery 21 CFR 878.4810 GEX - Powered Laser Surgical Instrument ONG - Powered Laser Surgical Instrument With Microbeam\Fractional Output	General & Plastic Surgery 21 CFR 878.4810 GEX - Powered Laser Surgical Instrument ILY - Lamp, Infrared Therapeutic Heating ONF - Powered light based non-laser surgical instrument with thermal effect
1540nm		
Applicator	BTL-754-4	Clear Skin Pro
Indications for Use	The BTL-754-4 with 1540nm in Macro mode is intended for use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue.	Clear Skin Pro 1540nm Applicator: The ClearSkin Pro 1540nm is indicated for: Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.
Laser source	Er:Glass	Er:Glass
Wavelength	1540 nm	1540 nm
Output mode	Pulsed	Pulsed
Pulse width	2-8 ms	3 ms
Repetition rate	1.5 Hz	1-3 Hz
Application pattern (dots)	9.6 x 9.6 mm (69mB/cm^2) 64 mB/pulse	9.25 x 9.25 mm (57mB/cm^2) 49 mB/pulse
Microbeam size	1300 µm ±30%	1270 µm
Energy/ microbeam	Up to 30.5 mJ/mB	Up to 6-82 mJ/mB
Max. Fluence per Pulse	0.4 - 2.4 J/cm^2	0.5 – 6.5 J/cm^2

510(k) number **Device name** **Company name**	**K252561** **BTL-754FF** **BTL Industries, Inc.**	**K153229** **SUPERBIUM** **Bios s.r.l.**	**K150140** **Dermablate** **Asclepion**
Type	Subject device	Predicate 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	General & Plastic Surgery 21 CFR 878.4810 GEX - Powered Laser Surgical Instrument
Applicator	BTL-754-1	Er:Yag Handpiece	Dermablate Handpiece
Indications for Use	The BTL-754-1 with 2940nm is intended for use in Coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes). Laser skin resurfacing procedures for the treatment of: • Acne scars • Wrinkles	Coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes). Laser skin resurfacing procedures for the treatment of: • Acne scars • Wrinkles	Coagulation, vaporization, ablation or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry and Ophthalmology (skin around the eyes).

Laser source	Er:YAG	Er:YAG	Er:YAG
Wavelength	2940nm	2940nm	2940nm
Output mode	Pulsed	Pulsed	Pulsed
Pulse width	0.2 – 1.5 ms	0.2 – 2.2 ms	0.1 – 1 ms
Repetition rate	1.5-30 Hz	5 Hz	20 Hz
Application spot size	Ø 1 - 10 mm	Ø 1 mm & Ø 9 mm	Ø 1 mm & Ø 12 mm
Maximum Energy per Pulse	Up to 2.8 J	Up to 2.5 J	Up to 2.5 J
Fluence	356 J/cm^2 (@ 1 mm) 3.6 J/cm^2 (@ 10 mm)	318 J/cm^2 (@ 1 mm) 4 J/cm^2 (@ 9mm)	318 J/cm^2 (@ 1 mm) 1.9 J/cm^2 (@ 12mm)

510(k) number **Device name** **Company name**	**K252561** **BTL-754FF** **BTL Industries, Inc.**	**K023734** **Aramis II** **Quantel Medical**	**K032260** **Aramis II** **Quantel Medical**
Type	Subject device	Predicate 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 GEX - Powered Laser Surgical Instrument	General & Plastic Surgery 21 CFR 878.4810 GEX - Powered Laser Surgical Instrument
Applicator	BTL-754-1	Aramis II	Aramis II

Indications for Use	The BTL-754-1 with 1540nm is intended to be used for incision, excision, ablation, and coagulation (hemostasis) of soft tissue. The device is also indicated for the removal of pigmented lesions; photocoagulation of dermatological vascular lesions, including photothermolysis of blood vessels (treatment of facial and leg veins), for the treatment of periorbital and perioral wrinkles, for the treatment of back acne.	The Aramis II is intended to be used for incision / excision, ablation, and coagulation (homeostasis) of soft tissue. The Aramis II is also indicated for the removal of pigmented lesions; photocoagulation of dermatological vascular lesions, including photothermolysis of blood vessels (treatment of facial and leg veins), and for the treatment of periorbital and perioral wrinkles.	The ARAMIS II Dermatological Laser system, in addition to previously cleared indications, is intended for the treatment of back acne.
Laser source	Er:Glass	Er:Glass	
Wavelength	1540 nm	1540 nm	
Output mode	Pulsed	Pulsed	
Pulse width	2-8 ms	3 ms	
Repetition rate	1-4 Hz	1-7 Hz	
Application spot size	Ø 6-10 mm	Ø 4 mm	
Fluence per Pulse	@ 10 mm – @ 6 mm 3J/cm^2 – 8.5 J/cm^2	@4 mm 8, 10, 12 J/cm^2	

1540nm and 2940nm		
510(k) number **Device name** **Company name**	**K252561** **BTL-754FF** **BTL Industries, Inc.**	**K241270** **BTL-754** **BTL Industries, 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
Applicator	BTL-754-1	BTL-754-4
Indications for Use	The BTL-754-1 with combined 1540nm and 2940nm is intended for dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing, treatment of wrinklesc and textural irregularities.	The combined 1540nm and 2940nm 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.
Wavelenght	2940 nm laser	2940 nm laser
Pulse length range	0.2-1.5 ms	0.2-1.5 ms
Fluence	Up to 10 J/cm^2	Up to 50 J/cm^2
Wavelenght	1540 nm laser	1540 nm laser
Pulse length range	2-8 ms	4-7 ms
Fluence	Up to 8.5 J/cm^2	Up to 40 J/cm^2
Frequency range	1.5-4 Hz	1-3 Hz

Substantial Equivalence

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

Conclusion

Based upon the intended use and known technical information provided in this pre-market notification, the BTL-754FF device and its handpieces have been shown to be substantially equivalent to currently marketed predicate devices BTL-754 (K241270), Alma Harmony (K233024), Superbium (K153229), Dermablate (K150140), Dermablate (K210634), Aramis II (K023734) and Aramis II (K032260).