August 15, 2022

Biotec Italia, SRL
% Mike Berisha
Offical Correspondent
EVOSkin, LLC
6 Lincoln Knolll LN STE 100A
Burlington, Massachusetts 01803

Re: K212790
Trade/Device Name: XLase Plus
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, ONF
Dated: July 11, 2022
Received: July 14, 2022

Dear Mike Berisha:

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,

Jianting Wang
Acting 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)*
K212790

Device Name
XLase Plus

Indications for Use *(Describe)*
XLase Plus is indicated for use as follows:

Diode 808/760 nm 4000W ALEX PRO Handpiece: Indicated for the treatment of hair removal with static and dynamic modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.
• Treatment of Pseudofolliculitis barbae (PFB)
• Use on all skin types (Fitzpatrick I-VI).

SLP ND:YAG 1064 nm Handpiece: Indicated for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime. (Skin Types Fitzpatrick I-VI), photocoagulation and hemostasis of benign pigmented and benign vascular lesions, treatment of benign pigmented lesions, such as but not limited to warts, telangiectasia, leg veins and spider veins.

Q Switch ND:YAG 1064 nm Handpiece: Indicated for removal of dark tattoos and treatment of benign pigmented lesions.

CPL Handpiece: Indicated for use Fitzpatrick skin types I – IV, as shown in the table below. Indicated for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime. Photocoagulation of benign vascular lesions, photo thermolysis of blood vessels, treatment of benign pigmented lesions.

Pulsed light Wavelength range	Hair reduction	Benign Vascular lesions	Blood vessels	Benign Pigmented lesions
500-1200nm	-	Skin Types I, II	Skin Types I, II	-
520-1200nm	-	SkinType Ill	Skin Type III	Skin Types I, II
550-1200nm	Skin Types I, II	-	-	Skin Type Ill
595-1200nm	Skin Type Ill	-	-	-
650-1200nm	Skin Type IV	-	-	Skin Type IV

ERBIUM:YAG FRACTIONAL 2940 nm Handpiece: Indicated for procedure requiring resurfacing of soft tissue with fractionated handpiece.

Diode 2800W 810nm Handpiece: Indicated for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.
Indicated for:
- the treatment of benign vascular and benign pigmented lesions,
- permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Diode 1200W 810nm Handpiece:
Indicated for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.
Indicated for the treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions, and the treatment for pseudo folliculitis barbae.
Indicated for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Indicated for the treatment of benign pigmented lesions and leg veins.

ALEX 755nm Handpiece: Indicated for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.Treatment of benign pigmented lesions. Treatment of wrinkles and the photocoagulation of dermatological benign vascular lesions (such as port-wine stains, hemangiomas, telangiectasias). On all skin types (Fitzpatrick I- VI) including tanned skin.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

biotec Italia

510(k) Summary

This summary of 510(k) includes the safety and effectiveness information submitted in accordance with the requirements of 21 CFR 807.92

I. SUBMITTER

BIOTEC ITALIA S. r. l
Viale Della Repubblica 20
36031 Dueville VI, Italy

Email: info@biotecitalia.com
Tel.: +39 0444 591683
Fax: +39 0444 361032

Establishment Registration Number: currently not registered.

II. SUBMISSION CORRESPONDENT and AUTHORIZED DISTRIBUTOR

Mike Berisha
EVOSkin, LLC.
6 Lincoln Knoll Ln Ste 100A
Burlington, MA 01803-4729

Establishment Registration Number: currently not registered.
mike.berisha@evoskin.com
Phone: 1 (786) 778-0419

III. DATE SUMMARY PREPARED: August 12, 2022

IV. SUBJECT DEVICE

Trade Name (proprietary name): XLase Plus
Common or Usual Name: Medical Laser and Pulsed Light Platform
Classification Name: Powered Laser Surgical Instrument
Device Class: II
Regulation Number: 21 CFR 878.4810
Product Code: GEX, ONF

V. PREDICATE DEVICE

Trade Name: Deka Luxea
510k - K192539
El., EN. Electronic Engineering SPA
Via Baldanzese 17
Calenzano, IT 50041

VI. REFERENCE DEVICES

Trade Name: Elysion Pro
510k – K193367

Trade Name: LightSheer Duet
510k - K053628

Trade Name: Dynamis Pro Family
510k - K143723

Trade Name: GentleMax Pro Plus
510k - K201111

VII. DEVICE DESCRIPTION

XLase Plus, laser for medical applications. It features two models: XLase Plus Standing (with wheels) and XLase Plus Table (tabletop).

The two medical devices are identical, contain the same electronic boards and the same critical components, use the same software and are able to perform the same aesthetic treatments. The generic components of XLase Plus Table are a subset of those of XLase Plus Standing. The difference between the two devices is that XLase Plus Standing is built on wheels while XLase Plus Table has no wheels but can be easily placed on a table due to its low weight. The device is for prescription use only.

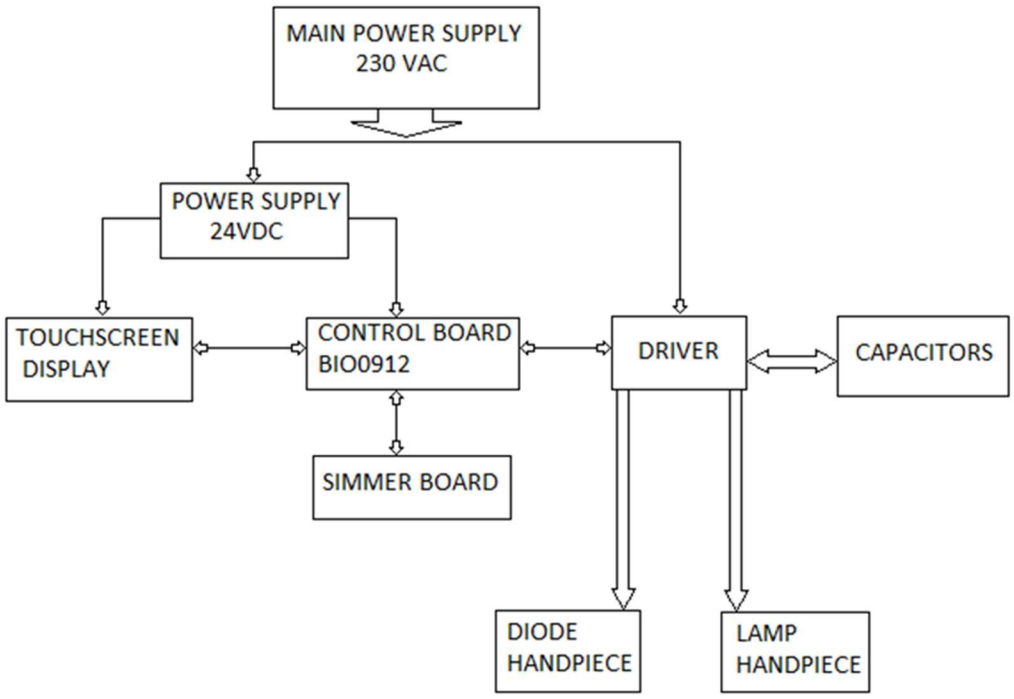
The XLase Plus Standing and XLase Plus Table medical devices consists of:

- System Console
- Operator control panel
- Touch screen monitor
- Power cable
- Accessories and components

Principles of Operation

The XLase Plus system principles of operation can be represented with the following block diagram:

XLase Plus Standing and Table (Consoles) Principles of Operation / Mechanism of Action:



Proposed Conditions of Use
Temperature: 10 °C to 40 °C Relative humidity: 30% to 75%

Technology
The XLase Plus offers the flexibility to perform different medical and aesthetic treatments due to different laser modules. Treatment parameters are set according to Indications for Use.

A range of values is available for each parameter. The integrated safety functions prevent the selection of values outside this range. However, because the settings of some parameters depend on other parameters, it is not always possible to use the full range of values for all parameters.

Spectrum and filter	
Handpiece Type	**Description**
CPL	The wavelength range and filters determine the depth of light penetration and the spectral selectivity associated with the target chromophores. The 50x10mm optical guide determines the covered surface if the distal end of the optical guide is positioned perpendicular to the patient's skin.
Laser	SLP ND:YAG 1064 nm: The size of the selected spacer determines the surface covered when the distal end of the tip is positioned perpendicular to the patient's skin. It will be chosen according to the characteristics of the vessel (diameter, depth).
	ERBIUM:YAG FRACTIONAL 2940 nm: The size of the selected spacer determines the covered surface of the treatment area that absorbs the laser energy when the distal end of the tip is positioned perpendicularly on the patient's skin.
	QSWITCH ND: YAG 1064 nm: The size of the selected spacer determines the surface covered when the distal end of the tip is positioned perpendicular to the patient's skin.
	ALEX 755nm: The size of the selected spacer determines the covered surface of the treatment area that absorbs the laser energy when the distal end of the tip is positioned perpendicular to the patient's skin
Diode handpiece*	Diode 808/760 nm 4000W ALEX PRO, Diode 810nm 2800W and Diode 810nm 1200W: The 10x10mm optical guide determines the covered surface if the distal end of the optical guide is positioned perpendicular to the patient's skin.

*CPL and Diode handpieces are equipped with an integrated cooling mechanism that provides continuous skin cooling through contact in the treatment area.

VIII. INDICATIONS FOR USE

XLase Plus is indicated for use as follows:

Diode 808/760 nm 4000W ALEX PRO Handpiece: Indicated for the treatment of hair removal with static and dynamic modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.
• Treatment of Pseudofolliculitis barbae (PFB)
• Use on all skin types (Fitzpatrick I-VI).

SLP ND:YAG 1064 nm Handpiece: Indicated for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime. (Skin Types Fitzpatrick I-VI), photocoagulation and hemostasis of benign pigmented and benign vascular lesions, treatment of benign pigmented lesions, such as but not limited to warts, telangiectasia, leg veins and spider veins.

Q Switch ND:YAG 1064 nm Handpiece: Indicated for removal of dark tattoos and treatment of benign pigmented lesions.

CPL Handpiece: Indicated for use Fitzpatrick skin types I – IV, as shown in the table below. Indicated for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime. Photocoagulation of benign vascular lesions, photo thermolysis of blood vessels, treatment of benign pigmented lesions.

Pulsed light Wavelength range	Hair reduction	Benign Vascular lesions	Blood vessels	Benign Pigmented lesions
500-1200nm	-	Skin Types I, II	Skin Types I, II	-
520-1200nm	-	SkinType Ill	Skin Type III	Skin Types I, II
550-1200nm	Skin Types I, II	-	-	Skin Type Ill
595-1200nm	Skin Type Ill	-	-	-
650-1200nm	Skin Type IV	-	-	Skin Type IV

ERBIUM:YAG FRACTIONAL 2940 nm Handpiece: Indicated for procedure requiring resurfacing of soft tissue with fractionated handpiece.

Diode 2800W 810nm Handpiece: Indicated for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin. Indicated for:
- the treatment of benign vascular and benign pigmented lesions,
- permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Diode 1200W 810nm Handpiece:
Indicated for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin.
Indicated for the treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions, and the treatment for pseudo folliculitis barbae.
Indicated for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.
Indicated for the treatment of benign pigmented lesions and leg veins.

ALEX 755nm Handpiece: Indicated for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.Treatment of benign pigmented lesions. Treatment of wrinkles and the photocoagulation of dermatological benign vascular lesions (such as port-wine stains, hemangiomas, telangiectasias). On all skin types (Fitzpatrick I- VI) including tanned skin.

IX. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

	Subject Device XLase Plus	**Predicate Device Deka Luxea** K192539	**Reference Device Elysion Pro** K193367	**Reference Device LightSheer Duet** K053628	**Reference Device Dynamis Pro Family** K143723	**Reference Device GentleMax Pro Plus** K201111
Medical Device Common Name	Medical Laser and Pulsed Light platform	Medical Laser and pulsed Light platform	Diode Laser Hair Removal System	Pulsed Diode Array Laser	Er:YAG/Nd:YAG Surgical Laser	Dermatology Laser System
Manufacturer:	BIOTEC ITALIA S.R.L.	DEKA M.E.L.A.	High Technology Products, S.L.U	LUMENIS LTD.	FOTONA	CANDELA CORPORATION
Console	XLase Plus Standing and Table	Deka Luxea	Elysion Pro	LightSheer Duet	Dynamis Pro	GentleMax Pro
Product Code	GEX, ONF	GEX, ONF	GEX	GEX	GEX, ONG	GEX
Configuration	•System Console •Operator control panel •Touch screen monitor •Laser handpiece(s) •Diode(s) handpiece(s)	•System Console •Operator control panel •Touch screen monitor •Laser handpiece(s) •Diode(s) handpiece(s)	•System Console •Operator control panel •Touch screen monitor •Diode handpiece	•System Console •Operator control panel •Touch screen monitor •Laser handpiece(s) •Diode(s) handpiece(s)	•System Console •Operator control panel •Touch screen monitor •Laser handpiece(s) •Diode(s) handpiece(s)	•System Console •Operator control panel •Touch screen monitor •Laser handpiece(s) •Diode(s) handpiece(s)
Emission Activation	Foot or finger switch	Foot or finger switch	Finger switch	Foot or finger switch	Foot or finger switch	Foot or finger switch
Electrical specifications	115-240v ~, 50-60Hz, 2300VA max.	115-240v ~, 50-60Hz, 2300VA max.	115-240v ~, 50-60Hz, 2300VA max.	115-240v ~, 50-60Hz, 2300VA max.	115-240v ~, 50-60Hz, 2300VA max.	115-240v ~, 50-60Hz, 2300VA max.
Operating Environment	Temperature: 10 °C to 40 °C Relative humidity: 30% to 75%	Temperature: 10 °C to 40 °C Relative humidity: 30% to 75%	Temperature: 18 °C to 28 °C	Temperature: 10 °C to 40 °C Relative humidity: 30% to 75%	Temperature: ambient temperature range +10 °C to +25 °C;	Temperature: 65° and 85°F (18° and 29°C). Relative humidity: 30% to 75%

					Relative humidity: 30% to 75% -non condensing	
Storage Conditions	Temperature (-10 – 38 ºC) or (-14 to 100 ºF). Relative humidity % range is 1.5% to 90%.	Temperature: 5 °C to 50 °C Relative humidity: 30% to 95%	Temperature: 2 – 50 °C Relative humidity <90% (without condensation)	Temperature: -5ºC – 55ºC 23ºF – 131ºF Relative humidity: 90% @ 35ºC, 32% @ 55ºC	Temperature: -40 ºC to +70 ºC (without cooling water) Relative humidity: 10% to 100% condensing	Temperature: 40° and 110° F (4.5° and 43°C). Relative humidity: 30% to 95%
Sterilization	N/A	N/A	N/A	N/A	N/A	N/A
Packaging	A wooden pallet: this pallet (80 x 65 x 11 cm for Table and 82 x 76 x 64 cm for) is made of wood treated according to ISPM-15 - Cardboard box on the outside; - Polyurethane foam - Transportation monitoring: Shockwave label Tiltwatch label Data logger (temperature and humidity)	Unknown	Unknown	Unknown	Unknown	Unknown
Body areas of application	Feet, Legs, Hip, Thigh, Abdomen, Chest, Shoulders, Back, Arms, Neck, Face and Hands	Feet, Legs, Hip, Thigh, Abdomen, Chest, Shoulders, Back, Arms, Neck, Face and Hands.	Feet, Legs, Hip, Thigh, Abdomen, Chest, Shoulders, Back, Arms, Neck, Face and Hands.	Feet, Legs, Hip, Thigh, Abdomen, Chest, Shoulders, Back, Arms, Neck, Face and Hands.	Feet, Legs, Hip, Thigh, Abdomen, Chest, Shoulders, Back, Arms, Neck, Face and Hands.	Feet, Legs, Hip, Thigh, Abdomen, Chest, Shoulders, Back, Arms, Neck, Face and Hands.
Duration of Body Contact	The material with direct tissue contact with the skin is the stainless steel from (spacers, and diode handpieces) with contact duration (A) for <= 24 hours.	Contact duration (A) for ≤ 24 hours.	Contact duration (A) for ≤ 24 hours.	Contact duration (A) for ≤ 24 hours.	Contact duration (A) for ≤ 24 hours.	Contact duration (A) for ≤ 24 hours.
User Interface	Display screen (software XLASE PLUS)	The Touch Screen/Display Panel provides a simple graphical user interface (GUI) from which you can set the operating mode, laser parameters DCD parameters,	The console provides touchscreen computer control	The console provides touchscreen computer control	Touch screen	The Touch Screen/Display Panel provides a simple graphical user interface (GUI) from which you can set the operating mode, laser parameters DCD parameters

Software	The human machine interface was developed with "Touch Win Edit Tool" The processor used is by ARM7 LCD MCU Display is a 208-LQFP - LPC2470FBD208 from semiconductor manufacturer NXP.	Unknown type	Unknown type	Unknown type	Unknown type	Unknown type
Handpieces						
Diode 808/760 nm 4000W ALEX PRO Handpiece	**Indications for Use**					
	Diode 808/760 nm 4000W ALEX PRO: Indicated for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime. • Treatment of Pseudofolliculitis barbae (PFB) • Use on all skin types (Fitzpatrick I-VI).		Elysion handpiece: Indications for use for ELYSION diode laser hair removal system with 755nm and 810nm applicators include: • Hair Removal with Static and Dynamic modes intended for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime. • Treatment of Pseudofolliculitis barbae (PFB) • Use on all skin types (Fitzpatrick I-VI).			
	Specifications					
	Product Code: GEX		Product Code: GEX			
	Laser Wavelength: 808, 760 nm		Laser Wavelength: 810 nm, 755 nm			
	Fluence: 32 J/cm2 ± 20 % (24 – 40 J/cm2)		Fluence: 40 J\cm^2			
	Handpiece Spot Size: Spot Size 15 mm - 15 x 10mm ± 20 % (12-18 x 8-12 mm) Spot Size 9 mm - 9 x 9 mm ± 20 % (7.2-10.8 x 7.2-10.8 mm)		Handpiece Spot Size: 10 x 10, 18 x 10mm			
	Pulse Duration: up to 120 ms Min Pulse Duration: 10 ms ± 20 % (8 - 12 ms) Max Pulse Duration 100 ms ± 20 % (80-120 ms)		Pulse Duration: 3 – 400 ms			

	Pulse Repetition Rate (Hz): 1 - 8 Hz ± 20 % (0.8 – 10.0 Hz) (Long Pulse or Static up) to 3 Hz (Motion Speed or Dynamic) up to 5 – 10 Hz		Pulse Repetition Rate (Hz): Static up to 3Hz Dynamic 5 - 15 Hz			
	Cooling Temperature: (Sapphire cooling) 5ºC		Cooling Temperature: (Sapphire cooling) 5ºC			
Laser SLP ND:YAG 1064nm Handpiece	**Indications for Use**					
	SLP ND:YAG 1064 nm Handpiece: Indicated for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime. (Skin Types Fitzpatrick I-VI), photocoagulation and hemostasis of benign pigmented and benign vascular lesions, treatment of benign pigmented lesions, such as but not limited to warts, telangiectasia, leg veins and spider veins.	**SPARKS LASER handpiece:** Indicated for removal of unwanted hair, for stable long term or permanent hair reduction (Skin Types Fitzpatrick I-VI), photocoagulation and hemostasis of benign pigmented and vascular lesions, such as but not limited to warts, telangiectasia, leg veins and spider veins, treatment of benign pigmented lesions.				
	Specifications					
	Product Code: GEX	Product Code: GEX				
	Laser Wavelength: 1064 nm	Laser Wavelength: 1064 nm				
	Fluence: (2.5 mm) 100-584 ± 20 % J\cm2 (80 – 700 J/cm2) (4 mm) 30-250 ± 20 % J\cm2 (24 – 300 J/cm2) (6 mm) - 50 – 136 J/cm2 ± 20 % (40 - 170 J/cm2) (10 mm) 4 – 48 ± 20 % J/cm2 (5 - 60 J/cm2)	Fluence: 80-700 J\cm^2 (2.5 mm) 30 -250 J\cm^2 (4 mm) 14-170 J\cm^2 (6 mm) 5-60 J\cm^2 (10 mm)				
	Handpiece Spot Size: Spot Size (2.5 mm) - 2.5 mm ± 20 % (2 - 3 mm)	Handpiece Spot Sizes: Ø 2.5, 4, 6, 10 mm				

	Spot Size (4 mm) - 4 mm ± 20 % (3.2 - 4.8mm) Spot Size (6 mm) - 6 mm ± 20 % (4.8 - 7.2 mm) Spot Size (10 mm) - 10 mm ± 20 % (8 - 12mm)					
	Pulse Duration: Min Pulse Duration – 250 us ± 20 % (200 - 300 us) = 0.25 ms ± 20 % (0.20 – 0.30 ms) Max Pulse Duration 50 ms ± 20 % (40 - 60 ms) = 50000 us ± 20 % (40000 - 60000 us)	Pulse Duration: 1 – 280 ms				
	Pulse Repetition Rate: 1 - 8 Hz ± 20 % (0.8 – 10.0 Hz)	Pulse Repetition Rate: Single shot to 10 Hz				
Laser QS ND:YAG 1064 nm Handpiece	**Indications for Use**					
	Laser QS ND:YAG 1064 nm: Indicated for removal of dark tattoos and treatment of benign pigmented lesions.	**PRISMA LASER handpiece:** Indicated for removal of dark tattoos and treatment of benign pigmented lesions.				
	Specifications					
	Product Code: GEX	Product Code: GEX				
	Laser Wavelength: 1064 nm	Laser Wavelength: 1064 nm				
	Fluence: (2.5 mm) - 17 J/cm^2 ± 20 % (13.6 - 20.4 J/cm^2)	Fluence: 14 J/cm^2 (2.5 x 2.5 mm), 9 J/cm^2 (3 x 3 mm)				
	Handpiece Spot Size: Spot Size (2.5 mm) - 2.5 mm ± 20 % (2 - 3mm)	Handpiece Spot Sizes: 2.5 x 2.5 mm, 3 x 3 mm				
	Pulse Duration: 9 ns ± 20 % (7.2 - 10.8 ns)	Pulse Duration: 9 ns				
	Pulse Repetition Rate: 0.8 – 4 Hz ± 20 % (1 – 5 Hz)	Pulse Repetition Rate: 1 to 5 Hz				
CPL Calibrated Pulsed Light Handpiece	**Indications for Use**					
	CPL Calibrated Pulsed Light: Indicated for use on Fitzpatrick skin types I – IV, as shown in the table below.	**LILAC** Pulsed Light handpiece: Permanent hair reduction. Photocoagulation of benign vascular				

	Indicated for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime. Photocoagulation of benign vascular lesions, photo thermolysis of blood vessels, treatment of benign pigmented lesions. Table 2 -CPL – Subject Device Wavelength Ranges	lesions, photo thermolysis of blood vessels, treatment of benign pigmented lesions. Refer to Table 1 -CPL – Predicate Device Wavelength Ranges				
	Specifications					
	Product Code: ONF	Product Code: ONF				
	Pulse Light Emission Spectrum: 500-1200nm, 520-1200nm, 550-1200nm, 595-1200nm, 650-1200nm	Pulse Light Emission Spectrum: 500 - l200 nm, 520 - l200 nm, 600 - l200 nm, 650 - l200 nm, 550 - l200 nm				
	Fluence: 0.8 - 20 J/cm^2 ± 20 % (1 - 25 J/cm^2)	Fluence: 1 - 25 J/cm^2				
	Handpiece Spot Size: Spot Size - 10 x 50 mm ± 20 % (8-12 x 40-60 mm)	Handpiece Spot Sizes: 48x13 mm				
	Pulse Duration: Min Pulse Duration 1 ms ± 20 % (0.8 - 1.2 ms) Max Pulse Duration 50 ms ± 20 % (40 - 60 ms)	Pulse Duration: 3 – 124 ms				
	Pulse Repetition Rate: 0.5 Hz max.	Repetition Rate: 0.5 Hz max.				
	Cooling Temperature: (Integrated Sapphire Cooling provided via handpiece light guide) 15-25ºC	Cooling Temperature: (Integrated Sapphire Cooling provided via handpiece light guide) 5-25ºC				
	Indications for Use					

ERBIUM:YAG FRACTIONAL 2940 nm handpiece	**ERBIUM:YAG FRACTIONAL 2940 nm** Indicated for procedure requiring resurfacing of soft tissue with fractionated handpiece				**Dynamis ER:YAG** Indicated for procedure requiring resurfacing of soft tissue with fractionated handpiece	
	Specifications (Handpiece with spacer for Fractional effects)					
	Wavelength: 2940nm				Wavelength: 2940nm	
	Pulse Duration: Min Pulse Duration 500 us ± 20 % (400 - 600 us) Max Pulse Duration 2 ms ± 20 % (1.6 - 2.4 ms) = 2000 us ± 20 % (1600 - 2400 us)				Pulse Duration: Min Pulse Duration: 0.1 ms Max Pulse Duration: 1.5 ms	
	Pulse Repetition Rate: 1 ± 20 % (0.8 – 1.2 Hz) – Nominal 1 Hz				Pulse Repetition Rate: 4 Hz	
	Spot Size (6 X6 mm, 9 X 9 mm) ± 20 %				Unknown	
	(Min-Max Energy): 1.0-7.85 mJ				unknown	
	Fractional Lens (spot Size): 6 x 6, 9 X 9				Fractional Lens (spot Size): 9X9 mm	
	Fractional Lens (shape of microbeams): Round				Fractional Lens (shape of microbeams): Round	
	Fractional Lens (microbeams diameter): 250 µm				Fractional Lens (microbeams diameter): 250 µm	
	Fractional Lens (distance between microbeams): 0.75 mm				Fractional Lens (distance between microbeams): 0.75 mm	
	Indications for Use					

Diode 2800W 810nm Handpiece	**Diode 2800W 810nm:** Indicated for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin. Indicated for -the treatment of benign vascular and pigmented lesions, - permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime.			**LightSheer Duet System with LightSheer ET 805nm Laser Handpiece:** Indicated for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin. Indicated for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions, and the treatment for pseudo folliculitis barbae. The LightSheer® DueffM Laser System with LightSheer® ET™ Laser Handpiece is also intended for hair removal, permanent hair reduction, and the treatment of benign pigmented lesions and leg veins.		
	Specifications					
	Product Code: GEX			Product Code: GEX		
	Laser Wavelength: 810 nm			Laser Wavelength: 790 -950 nm (800 nm Nominal)		
	Fluence: 10 - 100 J/cm^2 ± 20% (8 - 120 J/cm^2)			Fluence: 10 -100 J/cm^2		
	Pulse Duration Min Pulse Duration - 10 ms ± 20 % (8 - 12 ms) Max Pulse Duration - 400 ms ± 20 % (320 - 480 ms)			Pulse Duration: 5 - 400 ms		
	Pulse Repetition Rate: 0.8 – 2.4 Hz ± 20 % (1 - 3 Hz)			Pulse Repetition Rate: up to 3 Hz		
	Handpiece Spot Size: Spot Size (9 mm) - 9 x 9 mm ± 20 % (7.2 - 10.8 x 7.2 - 10.8 mm), Area= 81mm^2			Spot size: 9 x 9 mm, Area = 81 mm^2		
	Cooling Temperature: (Sapphire cooling) 5ºC			Cooling Temperature: (Sapphire cooling) 5ºC		
	Indications for Use					

Diode 1200W 810nm Handpiece	**Diode 1200W 810nm:** Indicated for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin. Indicated for the treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions, and the treatment for pseudo folliculitis barbae. Indicated for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime. Indicated for the treatment of benign pigmented lesions and leg veins.			**LightSheer Duet System with LightSheer ET 805nm Laser Handpiece:** Indicated for use on all skin types (Fitzpatrick skin types I – VI), including tanned skin. Indicated for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions, and the treatment for pseudo folliculitis barbae. The LightSheer® DueffM Laser System with LightSheer® ET™ Laser Handpiece is also intended for hair removal, permanent hair reduction, and the treatment of benign pigmented lesions and leg veins.		
	Specifications					
	Product Code: GEX			Product Code: GEX		
	Laser Wavelength: 810 nm			Laser Wavelength: 790 -950 nm (800 nm Nominal)		
	Fluence: 8 – 80 J/cm^2 ± 20 % (10 -100 J/cm^2)			Fluence: 10 -100 J/cm^2		
	Pulse Duration: Min Pulse Duration - 10 ms ± 20 % (8 - 12 ms) Max Pulse Duration - 60 ms ± 20 % (48 - 72 ms)			Pulse Duration: 5 - 400 ms		
	Pulse Repetition Rate: 0.8 – 2.4 Hz ± 20 % (1 - 3 Hz)			Pulse Repetition Rate: up to 3 Hz		
	Handpiece Spot Size: Spot Size (9 mm) - 9 x 9 mm ± 20 % (7.2 - 10.8 x 7.2 - 10.8 mm), Area = 81 mm^2			Spot size: 9 x 9 mm, Area = 81 mm^2		
	Cooling Temperature: (Sapphire cooling) 5ºC			Cooling Temperature: (Sapphire cooling) 5ºC		
ALEX 755nm Handpiece	**Indications for Use**					
	ALEX 755nm:					**Alessandrite 755nm:**

	Indicated for permanent reduction in hair regrowth, defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime. On all skin types (Fitzpatrick I- VI) including tanned skin. Treatment of benign pigmented lesions. Treatment of wrinkles and the photocoagulation of dermatological benign vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).					Temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. On all skin types (Fitzpatrick I- VI) including tanned skin. Treatment of benign pigmented lesions. Treatment of wrinkles. The photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).
	Specifications					
	Product Code: GEX					Product Code: GEX
	Laser Wavelength: 755nm					Laser Wavelength: 755nm
	Fluence: 44 J/cm^2 ± 20 % (35.2 - 53 J/cm^2)					Fluence: 53 J/cm2
	Handpiece Spot Size: Spot Size (2.5 mm) - 2.5 mm ± 20 % (2 - 3 mm) Spot Size (4 mm) - 4 mm ± 20 % (3.2 - 4.8mm) Spot Size (5 mm) - 5 mm ± 20 % (4.0 - 6.0 mm) Spot Size (6 mm) - 6 mm ± 20 % (4.8 - 7.2 mm) Spot Size (7 mm) - 7 mm ± 20 % (5.6 - 8.4 mm) Spot Size (10 mm) -					Handpiece Spot Size: 6 mm

	10 mm ± 20 % (8 - 12mm)					
	Pulse Duration Min Pulse Duration – 250 us ± 20 % (200 - 300 us) Max Pulse Duration 10 ± 20 % (8 - 12 ms) = 1000 ± 20 % (8000-12000 us)					Pulse Duration: 250us-100000 us
	Pulse Repetition Rate: 1 - 8 Hz ± 20 % (0.8 – 10.0 Hz)					Pulse Repetition Rate: up to 10Hz

Pulsed light Wavelength range	Hair reduction	Benign Vascular lesions	Blood vessels	Benign Pigmented lesions
500-1200nm	-	Skin Types I, II	Skin Types I, II	-
520-1200nm	-	Skin Type III	Skin Type III	Skin Types I, II
550-1200nm	Skin Types I, II	-	-	Skin Type III
600-1200nm	Skin Type Ill	-	-	-
650-1200nm	Skin Type IV	-	-	Skin Type IV

Table 1 - Predicate Device Wavelength Ranges

Pulsed light Wavelength range	Hair reduction	Benign Vascular lesions	Blood vessels	Benign Pigmented lesions
500-1200nm	-	Skin types I, II	Skin types I, II	
520-1200nm	-	Skin types III	Skin types III	Skin types I, II
550-1200nm	Skin types I, II	-	-	Skin types III
595-1200nm	Skin types III	-	-	-
650-1200nm	Skin types IV	-	-	Skin types IV

Table 2 - CPL – Subject Device Wavelength Range

X. NON-CLINICAL TESTING

The following non-clinical tests were performed to support substantial equivalence determination.

Biocompatibility Testing
Skin Sensitization (ISO 10993-10: 2010)
Irritation (ISO 10993-23: 2021)

Cytotoxicity (ISO 10993-5:2009)

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the XLase Plus and required accessories. The subject device and required accessories comply with the IEC 60601-1 standard for electrical safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing
Verification and validation testing was conducted on the software interface and firmware and the documentation provided is as recommended in the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The firmware and software interface for this device were considered as a "moderate" level of concern.

Performance Testing Bench
The performance of the XLase Plus has been verified according to Biotec Italia SRL, procedures for product design and development to ensure that the device emits set energy parameters within specifications, as intended.

XI. CLINCIAL TESTING

Clinical studies were not needed to support substantial equivalence.

XII. CONCLUSIONS

Based on the comparison and analysis above, the proposed subject device is determined to be Substantially Equivalent (SE) to the predicate device.