High Technology Products SLU
Mrs. Vardhini Kirthivas
Freyr Global Regulatory Solutions and Services
Level 4 Building No. H-08, Phoenix SEZ Phase 2
Gachibowli, Hyderabad, 500081 India

Re: K193367
Trade/Device Name: elysion-pro
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
Dated: November 22, 2019
Received: December 4, 2019

Dear Vardhini Kirthivas:

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,

Jessica Mavadia-Shukla
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K193367

Device Name
EL YSION Diode Laser Hair Removal System

Indications for Use *(Describe)*

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, defmed 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).

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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K193367_510(k) Summary

K193367_510(K) Summary (21 CFR 868.5160)

5.1 Submitter Information:

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Date Prepared:	March 7th, 2020

5.2 Device Identification

Trade Name**:**	elysion-pro
Common Name:	ELYSION Diode Laser Hair Removal System
Classification Name:	Powered Laser Surgical Instrument
510(K) Number	K193367

Table 4: Device Identification

Regulation No.	Product Code	Device Class
21 CFR 878.4810	GEX	Class II

5.3 Legally Marketed Equivalent Device

1. Primelase Excellence - K191321 by High Technology Products, S.L.U (Same company).
2. The Modified Alma Lasers XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano XL Soprano XL and Soprano ICE] – K140009 by Alma Lasers Ltd.
3. Lightsheer Desire; Lightsheer Desire Light; Lightsheer Duet; Lightsheer Infinity – K170179 by Lumenis Ltd.

5.4 Device Description

ELYSION diode laser hair removal system is a medical electrical equipment intended for hair removal treatment, the basic principle of which is selective photothermolysis, which consist in the specific destruction of a follicle due to an increase of the temperature induced by a high-powered beam of light which is selectively absorbed by the melanin.

The ELYSION equipment consists of a central unit and a set of 3 removable applicators. The ELYSION equipment emits laser radiation (near-infrared light with a wavelength range of 755 nm & 810 nm), pulsed through the laser aperture situated at the tip of the applicator.

The device applicator contains the diode which emits the laser energy whereas the power delivered, and the working frequency being controlled by the machine's central unit. The applicator emits the energy through a sapphire window, in contact with the skin throughout the treatment, aimed at damaging the hair follicle.

The device has three types of applicators differentiated by the emitted wavelength and the area of emission. Two of the applicators emitting radiation at 810 nm wavelength for two areas 10×10 mm^2 and 18×10 mm^2 and another one emitting radiation at 755 nm for an area of 10×10 mm^2. Two different operation modes are available: static mode and dynamic mode, which are differentiated basically by the frequency range defined for each mode (1-2-3 Hz for static and 5-10-15 Hz for dynamic).

The emission of energy is activated in the form of continuous pulses when pressing the applicator button. The applicator sapphire tip is cooled to a constant temperature to cool the skin, so that it partially anaesthetizes the tissue reducing the risk of damage to the epidermis during treatment.

5.5 Indications for Use

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)

5.6 Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

1. IEC 60601-1:2005/ (R)2012 and A1:2012 Ed 3.1, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
2. EN IEC 60601-1-2:2014 Ed 4.0, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
3. IEC 62304:2006 Ed.1.0 – Medical device software – software life cycle processes
4. IEC 60601-2-22:2012 Ed 3.1 – Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
5. IEC 60825 – 1:2007 Ed 2.0 – Safety of laser products - Part 1: Equipment classification, and requirements.
6. IEC 60601-1-6:2013 Ed 3.1 – Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
7. ISO 14971:2007 – Medical devices – Application of risk management to medical devices.
8. UNE-EN-ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity
9. UNE-EN-ISO 10993-10:2013, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity

5.7 Clinical Test Conclusion

No clinical study is included in this submission

5.8 Substantially Equivalent (SE) Comparison

Table 5: Comparison table

S. No.	Parameters for Substantial Equivalence	Soprano ICE (K140009)	Lightsheer Infinity (K170179)	Primelase Excellence (K191321)	ELYSION
1	Company	Alma Lasers, Ltd,	Lumenis Ltd.	High Technology Products SLU	High Technology Products SLU
2	Product Code	GEX	GEX	GEX	GEX
3	Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
4	Principle of Operation	AlGaAs Laser diode array	AlGaAs Laser diode array	AlGaAs Laser diode array	AlGaAs Laser diode array
5	Laser Wavelength	755nm, 810 nm	805nm, 1060 nm	755 nm, 810 nm, 810 – 1060 nm	755nm, 810 nm
6	Laser Contact	Sapphire window	Pure sapphire, AL2O3	Pure sapphire, AL2O3	Pure sapphire, AL2O3
7	Spot Sizes (mm x mm)	12x10, 15x10, 20x10	9x9, 27x9, 22x35	20x9, 30x9, 30x17	10x10, 18x10
8	Fluence (Energy Density)	120J/cm2	100 J/cm2	80 J/cm2	70 J/cm2
9	Maximum Fluence actually used (as per treatment table)	40 J/cm2	48 J/cm2	43 J/cm2	40 J/cm2
10	Frequency	UP TO 3 Hz (HR) 5 – 10 Hz (SHR)	Up to 3 Hz	UP TO 3 Hz (Static) 5 – 10 Hz (Dynamic)	UP TO 3 Hz (Static) 5 – 15 Hz (Dynamic)
11	Pulse Duration	3.3 – 200 ms	5 – 400 ms	3 – 400 ms	3 – 400ms
12	Treatment Mode	SHR, HR & LB	Repetitive impulses	Static & Dynamic	Static & Dynamic

13	Tissue Cooling	Contact continuous, thermo-electrical	Chilltip contact cooling	Contact continuous, thermo-electrical	Contact continuous, thermo-electrical
14	Cooling temperature	4ºC (39ºF)	2ºC - 12ºC	5ºC	5ºC
15	User Interface	LCD touchscreen	LCD touchscreen	LCD touchscreen	LCD touchscreen
16	Pulsing Control	Finger switch	Finger switch	Finger switch	Finger switch
17	Configuration	Main unit, Handpiece & Foot Control	Main unit and Handpiece	Main unit, Handpiece & Foot Control (Optional)	Main unit, Handpiece & Foot Control (Optional)
18	Laser Classification	Class IV	Class IV	Class IV	Class IV
19	Power Supply	120VAC, 11A, 50/60 Hz, single phase 220/230VAC, 6A, 50/60 Hz, single phase	100-240 VAC +/-10%, 15 A max. | 50/60 Hz.	Single phase, 100-240V 50-60HZ	Single phase, 100-240V 50-60HZ
20	Dimension	53 cm wide x 57 cm deep x 120 cm high	44 x 50 x 123 cm	1140 x 480 x 550 mm	650 x 500 x 450 mm
21	Weight	50 Kg (110 lbs)	58 Kg	75 Kg	38 Kg

5.9 Substantially Equivalent (SE) Conclusion

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