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

August 2, 2019

Re: K191321
Trade/Device Name: Primelase Excellence
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: April 25, 2019
Received: May 15, 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,

Neil R.P. Ogden,
Assistant Director, THT4A4
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191321

Device Name
PRIMELASE Diode Laser Hair Removal System

Indications for Use *(Describe)*
Indications for use for PRIMELASE diode laser hair removal system with 755nm, 810nm and 810 – 1060nm 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).

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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005_510(K) Summary (21 CFR 868.5160)

5.1 Submitter Information:

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Date Prepared:	April 25th, 2019
Prepared By	Sravan Kumar Manchikanti Freyr Global Regulatory Solutions and Services

5.2 Device Identification

Trade Name**:**	primelase excellence
Common Name:	PRIMELASE Diode Laser Hair Removal System
Classification Name:	Powered Laser Surgical Instrument

Table 1: Device Identification

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

5.3 Predicate Devices

1. 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.
2. Lightsheer Desire; Lightsheer Desire Light; Lightsheer Duet; **Lightsheer Infinity** – **K170179** by Lumenis Ltd.
3. InMode **Diolaze System** – **K180719** by InMode MD Ltd.

5.4 Device Description

PRIMELASE 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 PRIMELASE machine consists of a central unit and a set of 5 removable applicators. The PRIMELASE equipment emits laser radiation (beam infrared light with a wavelength range of 755 nm to 1060 nm, typically and most used 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 treatment can be provided in two modes, dynamic and static. Dynamic mode uses the low fluence & high frequency and is used for initial treatments. Static mode uses high fluence & low frequency and is used for residual hair removal.

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 PRIMELASE diode laser hair removal system with **755nm, 810nm and 810 – 1060nm 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: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
3. IEC 62304: Medical device software – software life cycle processes
4. IEC 60601-2-22: Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
5. IEC60601-1-6: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
6. IEC 60825 – 1: Safety of laser products - Part 1: Equipment classification and requirements.
7. ISO 14971: Medical devices – Application of risk management to medical devices.
8. ISO 10993-5: Biological Evaluation of Medical Device, Part 5-Tests for In Vitro cytotoxicity
9. ISO 10993-10: Biological Evaluation of Medical Device, Part 10-Test for irritation and skin sensitization

5.7 Clinical Test Conclusion

No clinical study is included in this submission.

5.8 Substantially Equivalence (SE) Comparison

Table 2: Comparison table

S. No.	Parameters for Substantial Equivalence	Soprano ICE (K140009)	Lightsheer Infinity (K170179)	InMode Diolaze XL System (K180719)	PRIMELASE
1	Company	Alma Lasers, Ltd,	Lumenis Ltd.	InMode MD Ltd.	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	Diode Laser	AlGaAs Laser diode array
5	Laser Wavelength	755 nm, 810 nm	805 nm, 1060 nm	810 nm 810/1064 nm 755/810 nm	755 nm, 810 nm, 810 – 1060 nm
6	Laser Contact	Sapphire window	Pure sapphire, AL2O3	Sapphire output window	Pure sapphire, AL2O3
7	Spot Sizes (CMxCM)	12x10, 15x10, 20x10	9x9, 27x9, 22x35	11x 27.5	20x9, 30x9, 30x17
8	Fluence (Energy Density)	120J/cm2	100 J/cm2	5-40 J/cm2	80 J/cm2
9	Maximum Fluence actually used (as per treatment protocols)	40 J/cm2	48 J/cm2	40 J/cm2	43 J/cm2
10	Frequency	UP TO 3 Hz (HR) 5 – 10 Hz (SHR)	Up to 3 Hz	1 – 2 Hz 5 Hz (Glide)	UP TO 3 Hz (static) 5 – 10 Hz (dynamic)
11	Pulse Duration	3.3 – 200 ms	5 – 400 ms	5-200 ms	3 – 400 ms/ AUTO (3 ms)
12	Treatment Mode	SHR, HR & LB	Repetitive impulses	Single, Continuous and Glide	Static & Dynamic
13	Tissue Cooling	Contact continuous, thermo-electrical	Chilltip contact cooling	Skin contact cooling	Contact continuous, thermo-electrical
14	Cooling temperature	4ºC (39ºF)	2ºC - 12ºC	7 - 12° C	5ºC

		TRADITIONAL 510(K)	**PRIMELASE**		
15	User Interface	LCD touch-screen	LCD touch-screen	LCD touch-screen	LCD touch-screen
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	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.	100 – 240 VAC 50/60 Hz,	Single phase, 100-240V 50-60 Hz
20	Dimension	53 cm wide x 57 cm deep x 120 cm high	44 x 50 x 123 cm	46cm W x 46cm D x 100cm H	1140 x 480 x 550 mm
21	Weight	50 Kg (110 lbs)	58 kg	32 Kg	75 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.