December 17, 2020

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

Re: K201594
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: June 8, 2020
Received: June 12, 2020

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,

Purva U. Pandya -S

Purva Pandya
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201594

Device Name
Primelase Excellence

Indications for Use *(Describe)*
Intended Use:
PRIMELASE Excellence is intended for use in dermatologic and general surgical procedures.

Indications for Use:
PRIMELASE Excellence System with 810nm Laser applicator is intended for:
• 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).
• Treatment of benign pigmented lesions

PRIMELASE Excellence System with 755nm Laser applicator is intended for:
• 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).
• Treatment of benign pigmented lesions

PRIMELASE Excellence System with 1060nm Laser applicator is intended for:
• 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).
• Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia, and other benign vascular lesions and leg veins.
• Treatment of wrinkles

PRIMELASE Excellence System with 810-1060nm Laser applicator is intended for:
• 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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5. 510(k) Summary

5.1. Submitter Information:

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Contact Person: Mr. Sergi Lozano
E-mail: slozano@cocoonmedical.com

Date Prepared: 14 December 2020

5.2. Device Identification:

Device Trade Name: Primelase Excellence
Device Common Name: PRIMELASE Excellence System
Classification Name: Powered Laser Surgical Instrument
Device Class: Class II
Regulation Number: 21 CFR 878.4810
Product Code: GEX

5.3. Predicate Devices:

Table 1 – List of Predicate Devices

Device Name	510(k) Number
Primelase Excellence	K191321
The Modified Alma Lasers XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano ^{XL} Soprano ^{XL} and **Soprano ^{ICE}**]	K172193

Device Name	510(k) Number
Lightsheer Desire; Lightsheer Desire Light; Lightsheer Duet; **Lightsheer Infinity**	K170179

5.4. Device Description

PRIMELASE Excellence is a diode laser device which consists of a central unit and external 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 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. Intended Use & Indications for Use

Intended Use

PRIMELASE Excellence is intended for use in dermatologic and general surgical procedures.

Indications for Use

PRIMELASE Excellence System with 810nm Laser applicator is intended for:

- 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).
- Treatment of benign pigmented lesions

PRIMELASE Excellence System with 755nm Laser applicator is intended for:

- 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).
- Treatment of benign pigmented lesions

PRIMELASE Excellence System with 1060nm Laser applicator is intended for:

- 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).
- Treatment of benign vascular lesions, including angiomas, hemangiomas, telangiectasia, and other benign vascular lesions and leg veins.
- Treatment of wrinkles

PRIMELASE Excellence System with 810-1060nm Laser applicator is intended for:

- 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. Comparison of Technological Characteristics

The fundamental scientific technology, materials of construction and mechanism of operation are identical between the subject PRIMELASE equipment and the predicate devices. Table 2 summarizes the comparison of technological characteristics between the subject and predicate devices.

Table 2 – Substantial Equivalence Table

S.No	Parameters	Soprano ICE (K172193)	Lightsheer Infinity (K170179)	Primelase Excellence (K191321)	Primelase Excellence (Subject device)
1.	Manufacturer	Alma Lasers, Ltd,	Lumenis Ltd	High Technology Products S.L.U.	High Technology Products, S.L.U.
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

S.No	Parameters	Soprano ICE (K172193)	Lightsheer Infinity (K170179)	Primelase Excellence (K191321)	Primelase Excellence (Subject device)
4.	Principle of Operation	AlGaAs Laser diode array	AlGaAs Laser diode array	AlGaAs Laser diode array	AlGaAs Laser diode array
5.	Laser Classification	Class IV	Class IV	Class IV	Class IV
6.	User Interface	LCD touch screen	LCD touch screen	LCD touch screen	LCD touch screen
7.	Pulsing Control	Finger switch	Finger switch	Finger switch	Finger switch
8.	Configuration	Main unit, Handpiece and Foot control	Main unit and Handpiece	Main unit, Handpiece and Foot control (optional)	Main unit, Handpiece and Foot control (optional)
9.	Laser Wavelength	755 nm 810 nm 1064nm	805 nm 1060 nm	755nm 810nm 810-1060nm	755nm 810nm 1060nm 810-1060nm
10.	Spot Size (CM × CM)	12x10, 15x10, 20x10, 10x10,	9x9, 27x9, 22x35	20x9, 30x9, 30x17	20x9, 30x9, 30x17 10x10
11.	Laser Contact	Sapphire window	Pure sapphire, Al2O3	Pure sapphire, Al2O3	Pure sapphire, Al2O3
12.	Frequency	Up to 3Hz (HR) 5 – 10Hz (SHR)	Up to 3Hz	Up to 3Hz (static) 5 – 10Hz (dynamic)	Up to 3Hz (static) 5 – 10Hz (dynamic)
13.	Pulse duration	3.3-200ms	5-400ms	3-400ms	3-400ms
14.	Fluence	120J/cm^2	100J/cm^2	80J/cm^2	120J/cm^2
15.	Tissue cooling	Contact continuous, Thermo-electrical	Chilltip contact cooling	Contact continuous, Thermo-electrical	Contact continuous, Thermo-electrical
16.	Cooling Temperature	4 ˚C	2 ˚C -12 ˚C	5˚C	5˚C
17.	Power supply	120VAC, 11A, 50/60	100-240 VAC +/- 10%,	Single phase, 100-240V 50-60 Hz	Single phase, 100-240V 50-60 Hz

S.No	Parameters	Soprano ICE (K172193)	Lightsheer Infinity (K170179)	Primelase Excellence (K191321)	Primelase Excellence (Subject device)
		Hz, single phase 220/230VAC, 6A, 50/60 Hz, single phase	15 A max. | 50/60 Hz.		

5.7. Non-Clinical Testing

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

1. IEC 60601-1:2005 + AMD1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2:2014 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/AMD:2015 Medical device software – software life cycle processes
4. IEC 60601-2-22 Edition 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. IEC60601-1-6 Edition 3.1: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
6. IEC 60825 – 1 Edition 2: Safety of laser products - Part 1: Equipment classification and requirements.
7. ISO 14971:2007 Medical devices – Application of risk management to medical devices.
8. ISO 10993-5:2009 Biological Evaluation of Medical Device, Part 5-Tests for In Vitro cytotoxicity
9. ISO 10993-10:2010 Biological Evaluation of Medical Device, Part 10-Test for irritation and skin sensitization

5.8. Clinical Testing

No clinical study is included in this submission.

5.9. Conclusion

Based on the comparison and analysis above, the PRIMELASE Excellence device's intended use and technological characteristics do not raise new types of questions regarding safety and efficacy when compared to the predicates. Based on its technical characteristics, indications for use, and performance data, the PRIMELASE Excellence device is considered to be substantially equivalent to the predicate devices.