Lumenis Ltd.
℅ Jonathan Kahan
Regulatory Counsel
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K193500
Trade/Device Name: Stellar M22 for Intense Pulsed Light (IPL) and Laser System
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, ONG
Dated: December 17, 2019
Received: December 17, 2019

Dear Jonathan Kahan:

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

Indications for Use Statement

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 on last page

510(k) Number *(if known)*

K193500

Device Name

Stellar M22 for Intense Pulsed Light (IPL) and Laser system

Indications for Use *(Describe)*

The subject Stellar M22 has connection capability with the following available treatment handpieces, for multi-application treatment options. All handpieces are designed for aesthetic and dermatological skin procedure applications, as follows:

- **The Intense Pulsed Light (IPL) handpiece with a spectrum of 400-1200 nm (with 9 different filters) is indicated for:**
    - Benign epidermal lesions, including dyschromia, hyperpigmentation, melasma, and ephelides (freckles)
    - Cutaneous lesions, including warts, scars and striae
    - Benign cutaneous vascular lesions, including port wine stains, hemoangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations
    - Removal of unwanted hair and to effect stable long term, or permanent* hair reduction in skin types I-V through selective targeting of melanin in hair follicles
    - Mild to moderate inflammatory Acne (Acne vulgaris)
- **The Nd:YAG Laser handpiece with a wavelength of 1064 nm (Multi-Spot Nd:YAG) is indicated for:**
    - The coagulation and hemostasis of vascular lesions and soft tissue, including the treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1-4.0 mm. diameter) of the leg
    - The removal of unwanted hair and to effect table long term, or permanent* hair reduction in skin types I-V through selective targeting of melanin in hair follicles
    - The non-ablative treatment of facial wrinkles
- **ResurFX module and handpiece, with wavelength of 1565 nm, is indicated for:**
    - Use in dermatological procedures requiring fractional skin resurfacing and

coagulation of soft tissue

- **The Q-Switched Nd:YAG Laser Handpiece with a wavelength of 1064 nm is indicated for:**
    - o Removal of dark tattoos
    - o Treatment of pigmented lesions

*Note

Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after completion of treatment regime.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Stellar M22 for Intense Pulsed Light (IPL) and Laser System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Contact Person: Shlomit Segman, RA Senior Manager

Date Prepared: December 17, 2019

Name of the device:

Stellar M22 for Intense Pulsed Light (IPL) and Laser system

Classification Name:

Powered Laser Surgical Instrument

Regulation Class:

Class II

Product Code:

GEX (21 C.F.R. § 878.4810)

Subsequent Product Codes:

ONF, ONG

Predicate Device:

M22 System (K170060)

Intended Use

The Lumenis Stellar M22 has connection capability with the following available treatment handpieces, for multi-application treatment options. All handpieces are designed for aesthetic and dermatological skin procedure applications, as follows:

- **The Stellar Intense Pulsed Light (IPL) handpiece with a spectrum of 400-1200 nm (with 9 different filters) is indicated for:**
    - Benign epidermal lesions, including dyschromia, hyperpigmentation, melasma, and ephelides (freckles)
    - Cutaneous lesions, including warts, scars and striae
    - Benign cutaneous vascular lesions, including port wine stains, hemoangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations
    - Removal of unwanted hair and to effect stable long term, or permanent* hair reduction in skin types I-V through selective targeting of melanin in hair follicles
    - Mild to moderate inflammatory Acne (Acne vulgaris)
- **The Nd:YAG Laser handpiece with a wavelength of 1064 nm (Multi-Spot Nd:YAG) is indicated for:**
    - The coagulation and hemostasis of vascular lesions and soft tissue, including the treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1-4.0 mm. diameter) of the leg
    - The removal of unwanted hair from all skin types, and to effect table long term, or permanent* hair reduction in skin types I-V through selective targeting of melanin in hair follicles
    - The non-ablative treatment of facial wrinkles
- **ResurFX module and handpiece, with wavelength of 1565 nm, is indicated for:**
    - Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue
- **The Q-Switched Nd:YAG Laser Handpiece with a wavelength of 1064 nm is indicated for:**
    - Removal of dark tattoos
    - Treatment of pigmented lesions

*Note: Permanent hair reduction is defined as long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after completion of treatment regime.

Device Description

The subject Stellar M22 for Intense Pulsed Light (IPL) and Laser System is a multi-application, multi-technology platform with four (4) available treatment handpieces:

- Stellar Intense Pulsed Light (IPL) handpiece;
- Multi-Spot Nd:YAG laser handpiece;
- ResurFX non-ablative laser handpiece;
- Q-Switched Nd:YAG laser handpiece.

The following accessories are provided with and/or may be purchased independently for each of the four (4) available treatment handpieces of the Stellar M22 for Intense Pulsed Light (IPL) and Laser Systems:

- The Stellar IPL handpiece has nine (9) different filters available: Cut-off filters of 515, 560, 590,615, 640, 695 and 755 nm, Notch Filters of 400-600 & 800-1200 nm and 530-650& 900-1200 nm. Further, the IPL handpiece has three (3) Sapphire Cool LightGuides available with sizes of: 15mm x 35mm, 8mm x 15 mm, 6 mm diameter.

- The Multi-Spot Nd:YAG handpiece has three (3) different LightGuides available in sizes of: 2mm x 4mm, 6 mm, and 9 mm.

- The ResurFX handpiece has two (2) different treatment tips available: SapphireCool and Precision tips

- The Q-Switched Nd:YAG handpiece has both disposable and gold plated metal treatment tips available. The disposable treatment tips and metal treatment tips are available in seven (7) different sizes of: 2, 2.5, 3.5, 4, 5, 6 and 8 mm.

Technological Characteristics

The intended use and indications for use of the Stellar M22 for Intense Pulsed Light (IPL) and Laser Systems are the same as the predicate device. In addition, the same technological characteristics and principles of operation apply for the Stellar M22 for Intense Pulsed Light (IPL) and Laser Systems and the predicate device.

Comparison table of the technological characteristics of the Stellar M22 for Intense Pulsed Light (IPL) and Laser System compared to the predicate device is provided below:

	Stellar M22 (subject device)	**Cleared M22 and ResurFX Systems (K170060)**	**Comparison**
Principle of Operation	Selective photothermolysis	Selective photothermolysis	Same as predicate
Device Components	System console Four (4) available treatment handpieces: • Stellar Intense Pulsed Light (IPL)	System console Four (4) available treatment handpieces: • Universal Intense Pulsed Light (IPL)	Same as predicate

	• Multi-Spot Nd:YAG laser handpiece • Q-Switched Nd:YAG laser handpiece • ResurFX non-ablative laser module and handpiece	• Multi-Spot Nd:YAG laser handpiece • Q-Switched Nd:YAG laser handpiece • ResurFX non-ablative laser module and handpiece	
Monitor Display	12”	8.4”	Substantially equivalent
Software operating system	Windows 10 Embedded	Windows CE 5	Substantially equivalent
IPL Handpiece			
Wavelength	400-1200 nm	400-1200 nm	Same as predicate
Pulse duration (msec)	Up to 20 msec – single pulse	Up to 20 msec – single pulse	Same as predicate
Operational wavelengths	The IPL handpiece comes with 9 filters for various wavelengths: • Cut-off filters: 515, 560, 590, 615, 640, 695, 755 nm • Acne Filter (Notch filter 400-600 and 800-1200) • Vascular Filter (Notch filter 530-650 & 900-1200)	The IPL handpiece comes with 10 filters for various wavelengths: • Cut-off filters: 515, 560, 590, 615, 640, 695, 755 nm • Acne Filter (Notch filter 400-600 and 800-1200) • Vascular Filter (Notch filter 530-650 & 900-1200) • KTP filter (525-585 nm)	Same as predicate but without the KTP filter
SapphireCool LightGuides	Height: 55 mm	Height: 40 mm	Substantially equivalent – minor modification to dimension
Spot sizes (cm^2)	8x15 mm (1.20 cm^2) 15x35 mm (5.25 cm^2) 6 mm round (0.3 cm^2)	8x15 mm (1.20 cm^2) 15x35 mm (5.25 cm^2) 6 mm round (0.3 cm^2)	Same as predicate
Maximum Fluence	Up to 35 or 56 J/cm^2, upon tip size	Up to 35 or 56 J/cm^2, upon tip size	Same as predicate
Pulse Rate [Hz]	Up to 1 Hz	Up to 1 Hz	Same as predicate
Multiple Sequential Pulsing	Yes, 1, 2, and 3 pulses, varying fluence per pulse (AOPT mode)	Yes, 1, 2, and 3 pulses, varying fluence per pulse (AOPT mode)	Same as predicate
Contact sapphire cooling temperature	0 to10 °C (Rectangular) 0 to 15°C (Round)	4 to 10°C	Substantially Equivalent -

Treatment screens	Treatment present with additional basic treatment presets	Treatment present	Substantially equivalent – Minor software update to platform
LightGuide recognition	Yes	N/A	Substantially Equivalent – Addition of minor Hardware and software features to recognize connected fibers
Multi-Spot Nd:YAG Handpiece			
Operational Wavelength	1064 nm	1064 nm	Same as predicate
Spot sizes (mm)	2x4, 6, 9	2x4, 1.5, 6, 9	Substantially Equivalent
Maximum Fluence	Up to 225 J/cm^2 upon tip size (due to removal of the 1.5 mm tip)	Up to 600 J/cm^2 upon tip size	Substantially Equivalent
Pulse rate	Up to 1 Hz	Up to 1 Hz	Same as predicate
Multiple Sequential Pulsing	1, 2, and 3	1, 2, and 3	Same as predicate
Contact sapphire cooling temperature	-4 to 10 °C	4 to 10°C	Substantially Equivalent
ResurFX Handpiece			
Operational Wavelength	1565 nm	1565 nm	Same as predicate
Maximum Energy	Up to 40 or 70 mJ per micro-beam, upon tip	Up to 40 or 70 mJ per micro-beam, upon tip	Same as predicate
Type of Laser	Er:Glass Fiber-laser with scanner	Er:Glass Fiber-laser with scanner	Same as predicate
Tip treatment width	18 mm Sapphire Cool Tip 18 mm Precision Tip	18 mm Sapphire Cool Tip 18 mm Precision Tip	Same as predicate
Scanner	Dual axis scanner	Dual axis scanner	Same as predicate
Scanner shapes	Line, square, rectangle, circle, donut, hexagon, vertical line, and vertical rectangle	Line, square, rectangle, circle, donut, hexagon, vertical line, and vertical rectangle	Same as predicate
Treatment screens	Treatment present with additional basic treatment presets	Treatment present	Substantially equivalent – Minor software update to platform
Q-Switched Nd:YAG Handpiece			
Operational Wavelength	1064 nm	1064 nm	Same as predicate

Spot sizes (mm, diameter)	Disposable tips: 2.0, 2.5, 3.5 and 5.0 mm Gold plated metal tips: 2.0, 2.5, 3.5, 4.0, 5.0, 6.0 and 8.0 mm	Disposable tips: 2.0, 2.5, 3.5 and 5.0 mm Gold plated metal tips: 2.0, 2.5, 3.5, 4.0, 5.0, 6.0 and 8.0 mm	Same as predicate
Maximum Fluence	Up to 14 J/cm^2, upon tip size	Up to 14 J/cm^2, upon tip size	Same as predicate
Pulse Duration (nsec)	6-8	6-8	Same as predicate
Pulse Rate (Hz)	0.5-5.0	0.5-5.0	Same as predicate
Software			
Remote access capabilities	Yes	N/A	Substantially Equivalent – Addition of minor software features for internal company use

Performance Data

The following tests were performed to validate the modifications to the device:

- Design verification and validation testing
- Risk analysis activities in compliance with ISO 14971
- Electrical safety in accordance with IEC 60601-1 and EMC in accordance with IEC 60601-1-2
- IPL compatibility testing as required to conform with IEC 60601-2-57
- Software verification and validation

Conclusions

Stellar M22 for Intense Pulsed Light (IPL) and Laser system has the same intended use and similar indications, principles of operation, and technological characteristics as M22 System. The minor differences in the Stellar M22 for Intense Pulsed Light (IPL) and Laser system's technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the Stellar M22 for Intense Pulsed Light (IPL) and Laser system is as safe and effective as M22 System. Thus, the Stellar M22 for Intense Pulsed Light (IPL) and Laser system is substantially equivalent to its predicate devices.