April 16, 2025

Lumenis Be Ltd.
Shlomit Segman
AVP, RA-QA Product Life Cycle (PLC)
9 Hakidma Street PO Box 426, Yokneam Industrial Park
Yokneam, 2069236
Israel

Re: K250809
Trade/Device Name: Stellar M22
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: March 10, 2025
Received: March 17, 2025

Dear Shlomit Segman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250809

Device Name

Stellar M22

Indications for Use *(Describe)*

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

● Universal IPL with a spectrum of 400-1200nm (with different filters) is indicated for:

o Benign epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles).

o Cutaneous lesions, including warts, scars and striae.

o Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.

o Removal of unwanted hair from all skin types, and to effect stable long term, or permanent hair reduction* in skin types I-V through selective targeting of melanin in hair follicles.

o Mild to moderate inflammatory Acne (Acne Vulgaris).

● Multi-Spot Nd:YAG Laser, with a wavelength of 1064 nm is indicated for:

o 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.

o The non-ablative treatment of facial wrinkles.

o The removal of unwanted hair from all skin types, and to effect stable long term, or permanent hair reduction* in skin types I-V through selective targeting of melanin in hair follicles.

● The 1565nm ResurFX module, with a wavelength of 1565 nm, is indicated for:

o Use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue.

● Q-Switched Nd:YAG Laser, with a wavelength of 1064 nm, is indicated for:

o Treatment of pigmented lesions.

o Removal of dark tattoos.

(*) 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 regimen.

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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LUMENIS

510(K) SUMMARY K250809

Stellar M22 System

Applicant Name:	Lumenis Be Ltd. 9 Hakidma Street PO Box 426 Yokneam Industrial Park, Yokneam 2069236, Israel Tel: +972-77-9599000
Contact Person:	Shlomit Segman, Lumenis Be Ltd. 9 Hakidma Street PO Box 426 Yokneam Industrial Park, Yokneam 2069236, Israel Tel: +972-77-9599230 Email:Shlomit.Segman@lumenis.com
Date Prepared:	August 05, 2024
Trade Name:	Stellar M22
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Product Code:	GEX, ONF, ONG
Device Class:	Class II
Regulation Number:	21 CFR 878.4810
Panel:	General & Plastic Surgery
Predicate Devices:	K193500 (Stellar M22 for Intense Pulsed Light (IPL) and Laser System)

Intended Use/ Indications for Use:

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

- IPL with a spectrum of 400-1200nm (with 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, hemangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.

- Removal of unwanted hair from all skin types, 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).

● Multi-Spot Nd:YAG Laser, with a wavelength of 1064 nm 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 non-ablative treatment of facial wrinkles.
- The removal of unwanted hair from all skin types, and to effect stable long term, or permanent hair reduction* in skin types I-V through selective targeting of melanin in hair follicles.

● The 1565nm ResurFX module, with a wavelength of 1565 nm, is indicated for:

- Use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue.

● Q-Switched Nd:YAG Laser, with a wavelength of 1064 nm, is indicated for:

- Treatment of pigmented lesions.
- Removal of dark tattoos.

(*) 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 regimen.

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Device Description

The Lumenis Stellar M22 System is multi-application, multi-technology system intended for use in aesthetic dermatologic procedures.

The Stellar M22 System operates with four (4) treatment handpieces options (for connection capability), within serial operational mode:

- Intense Pulsed Light (IPL) handpiece;
- Multi-Spot Nd:YAG Laser handpiece;
- ResurFX Laser module and 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 530650& 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 are available in four (4) different sizes of: 2, 2.5, 3.5, and 5 mm, while the metal treatment tips are available in seven (7) different sizes of: 2, 2.5, 3.5, 4, 5, 6 and 8 mm.

Substantial Equivalence Discussion

The Stellar M22 system is a modification to the previously cleared Stellar M22 for Intense Pulsed Light (IPL) and Laser (predicate device, K193500).

The modifications introduced to the Stellar M22 system is mainly due to the addition of new Hardware to serve marketing, business and serviced purposes. Moreover, to maintain Lumenis' high-level service capabilities to the professional end-users and their patients, through establishment of a secure transmission of technical information to the cloud for further analysis and rapid problem-solving.

The modified system is substantially equivalent to the previously cleared Stellar M22 for Intense Pulsed Light (IPL) and Laser.

The Table below provides a comparison of the subject device to its predicate.

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Parameter	Predicate device Stellar M22 for Intense Pulsed Light (IPL) and Laser (K193500)	Subject device Stellar M22
Product Code	GEX, ONF, ONG	GEX, ONF, ONG
Regulation	21 CFR 878.4810	21 CFR 878.4810
Rx/OTC	Rx	Rx
Indications for Use	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 Lumenis Stellar M22 system has connection capability with the following available treatment modules, for multi-application treatment options. All modules are designed for aesthetic and dermatological skin procedure application, as follows: IPL with a spectrum of 400-1200nm (with 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, hemangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. • Removal of unwanted hair from all skin types, 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).

Parameter	Predicate device Stellar M22 for Intense Pulsed Light (IPL) and Laser (K193500)	Subject device Stellar M22
	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: • 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.	Multi-Spot Nd:YAG Laser, with a wavelength of 1064 nm 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 non-ablative treatment of facial wrinkles. • The removal of unwanted hair from all skin types, and to effect stable long term, or permanent hair reduction* in skin types I-V through selective targeting of melanin in hair follicles. The 1565nm ResurFX module, with a wavelength of 1565 nm, is indicated for: • Use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue. Q-Switched Nd:YAG Laser, with a wavelength of 1064 nm, is indicated for: • Treatment of pigmented lesions. • Removal of dark tattoos. *Note: 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 regimen.
Device Configuration	System console Four (4) available treatment handpieces:	System console Four (4) available treatment handpieces:

Parameter	Predicate device Stellar M22 for Intense Pulsed Light (IPL) and Laser (K193500)	Subject device Stellar M22
	• Stellar Intense Pulsed Light (IPL) • Multi-Spot Nd:YAG laser handpiece • Q-Switched Nd:YAG laser handpiece • ResurFX non-ablative laser module and handpiece	• Stellar Intense Pulsed Light (IPL) • Multi-Spot Nd:YAG laser handpiece • Q-Switched Nd:YAG laser handpiece • ResurFX non-ablative laser module and handpiece
Wavelength	400-1200 nm	400-1200 nm
Maximum Energy	Up to 40 or 70 mJ per micro-beam, upon tip	Up to 40 or 70 mJ per micro-beam, upon tip

Summary of Bench Verification

To support the Stellar M22 System, the following activities were performed:

- Risk analysis per ISO 14971
- Electrical, laser and electromagnetic compatibility safety testing according to IEC 60601-1 and IEC 60601-1-2
- Software verification and validation according to IEC 62304 and FDA Guidance “Principles of Software Validation Guidance for Industry and FDA Staff, January 2002”.
- System testing (e.g., Performance, functionality, communication).

Summary of Clinical Validation

No new clinical validation was required to support the Stellar M22 as the clinical validation of the Lumenis predicate device also applies to the subject device.

Conclusion

The subject device does not raise different types of safety or effectiveness questions. The conclusions drawn from these testing, and previously conducted testing of the predicate and legacy devices, demonstrate that the subject device is as safe, as effective, and performed as well as the predicate.

Thus, the subject device is substantially equivalent to its predicate.