DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 9, 2017

Lumenis, Ltd.
Naama Jacoby
Head Of RA Ophthalmic & M22 Platforms
6 Hakidma Street
Po Box 240
Yokneam, 2069204 IL

Re: K170060
Trade/Device Name: M22 And Resurfx Systems
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: August 7, 2017
Received: July 17, 2017

Dear Naama Jacoby:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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 on last page

510(k) Number *(if known)*

K170060

Device Name

Lumenis Family of IPL and Laser Systems: M22 and ResurFx Systems

Indications for Use *(Describe)*

The subject Lumenis M22 System 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 400-1200nm (with 10 different filters) is indicated for**:
  - Benign epidermal lesions, including dyschromia, hyperpigmentation, melasma, ephelides (freckles) and tattoos
  - 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)

- **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 stable 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 1064nm 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 the completion of a treatment regime.

The ResurFX System with wavelength of 1565 nm, is indicated for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.

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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510(k) SUMMARY

Lumenis Family of IPL and Laser Systems: M22 & ResurFX Systems

Applicant Name:	Lumenis Ltd. 6 Hakidma Street PO Box 240 Yokneam Industrial Park, Yokneam 2069204, Israel Tel: +972-4-9599000 Fax: +972-4-9599046
Contact Person:	Naama Jacoby - Head of RA, Ophthalmic & M22 Platforms 6 Hakidma Street PO Box 240 Yokneam Industrial Park, Yokneam 2069204, Israel Tel: +972-4-9599085 Fax: +972-4-9599198 Mail: **Naama.Jacoby@lumenis.com**
Date Prepared:	August 07, 2017
Trade Name:	Lumenis Family of IPL and Laser Systems: M22 & ResurFX Systems
Classification Name:	Powered laser surgical instrument
Product Code:	GEX, ONF, ONG
Device Class:	Class II
Regulation Number:	21 CFR 878.4810
Panel:	General & Plastic Surgery
Predicate Device:	M22 System, cleared under K142860 ResurFX module, cleared under K130028
Indications for Use:	The complete phrasing of the indications for use statement for the Lumenis Family of IPL and Laser Systems, combining both the M22 and ResurFX Systems, is provided in the formal Indications for Use Statement (FDA Form 3881).

From this point on, the 510(k) summary addresses the M22 System and the ResurFX System separately as follows:

M22 System

Indications for Use:

The subject **Lumenis M22 System** 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 400-1200nm (with 10 different filters) is indicated for:**
  - Benign epidermal lesions, including dyschromia, hyperpigmentation, melasma, ephelides (freckles) and tattoos
  - 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)

- **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 stable 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 1064nm 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 the completion of a treatment regime.

Device Description:

The subject Lumenis M22 System is a multi-application, multi-technology platform with four (4) available treatment handpieces:

- Universal 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 M22 System:

- The Universal IPL handpiece has ten (10) 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, and a Narrow band filter of 525-585 nm. Further, the IPL handpiece has three (3) sapphire cool light guides available with sizes of: 15mm x 35mm, 8mm x 15 mm, 6mm diameter.
- The Multi-Spot Nd:YAG handpiece has four (4) different light guides/tips available in sizes of: 2mm x 4mm, 6 mm, 9 mm and 1.5 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. The metal treatment tips are available in seven (7) different sizes of: 2, 2.5, 3.5, 4, 5, 6 and 8 mm.

Technological Characteristics and Substantial Equivalence:

The intended use and indications for use of the M22 System are the same as the selected predicate devices. In addition, the same technological characteristics and principles of operation apply for the M22 System and the predicate device.

The Lumenis M22 System main modification that have been made are:

- Addition of the IPL AOPT (Advanced Optimal Pulse Technology) Operation Mode that assists the physician in specifically tailoring the treatment to the patient's needs.
- Addition of new accessories to the IPL Handpiece – a Vascular Filter and a KTP filter.
- Addition of a new 6mm diameter light guide to the IPL Handpiece
- Addition of 4mm and 8 mm tips to the Q-switched Nd:YAG handpiece.
- Addition of a new 18mm Precision tip to the ResurFX handpiece.

- Addition of scanning shapes to the ResurFX handpiece – Vertical line and rectangle.
- Additional Lumenis software presets for user convenience.
- Software Upgrade to support the specified modifications.

These modifications have been introduced in order to configure a system that improves user convenience or increase their control of the delivered treatment.

Comparison table of technological characteristics of the Lumenis M22 System compared to those of the predicate device is provided below. The new accessories and features are bolded.

Device / Feature	**Lumenis M22 System (K142860) (Predicate Device)**	**Lumenis M22 System (K170060) (Subject Device)**
IPL Handpiece		
Wavelength	400 -1200 nm	Same
Pulse Duration (msec)	Up to 20 msec - single pulse 40-100 msec - multiple pulse	Same
Operational Wavelengths	The IPL handpiece comes with 8 filters for various wavelengths: Cut-off filters: 515, 560, 590, 615, 640, 695, 755 nm Acne Filter (Notch filter 400-600 and 800-1200 nm)	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 nm) **Vascular Filter (Notch filter 530-650 & 900-1200 nm)** **KTP filter (525-585 nm)**
Spot sizes (cm^2)	● 8 mm x 15 mm ● 15 mm x 35 mm	● 8mm x 15 mm ● 15 mm x 35 mm ● **6 mm round**
Max Fluence	Up to 35 J/cm^2	Up to 35 or **56 J/cm^2**, upon tip size
Pulse Rate [Hz]	Up to 1 Hz	Same
Multiple Sequential Pulsing	1, 2 and 3 pulses	1, 2 and 3 pulses, **varying fluence per pulse (AOPT mode)**
Multi-Spot Nd:YAG Handpiece		
Operational Wavelengths	1064 nm	Same
Spot sizes (mm)	2 x 4, 1.5, 6, 9	Same
Max Fluence	Up to 600 J/cm^2, upon tip size	Same
Pulse Rate [Hz]	Up to 1 Hz	Same
Multiple Sequential Pulsing	1, 2 and 3 pulses	Same
ResurFX Handpiece		
Operational Wavelengths	1565nm	Same
Max Energy	up to 70mJ per micro- beam	up to **40** or 70mJ per micro- beam, upon tip
Type of laser	Er:Glass Fiber-laser with scanner	Same
Tip treatment width	18mm SapphireCool Tip	18 mm SapphireCool Tip **18 mm Precision Tip**
Scanner	Dual axis scanner	Same
Scanning shapes	Line, square, rectangle, circle, donut, hexagon	Line, square, rectangle, circle, donut, hexagon, **vertical line, and vertical**

Feature \ Device	Lumenis M22 System (K142860) (Predicate Device)	Lumenis M22 System (K170060) (Subject Device)
		rectangle
Q-Switched Nd:YAG Handpiece		
Operational Wavelengths	1064 nm	Same
Spot sizes (mm, diameter)	2, 2.5, 3.5, 5, 6	2, 2.5, 3.5, **4**, 5, 6, **8**
Max Fluence	Up to 14 J/cm^2, upon tip size	Up to 14 J/cm^2, upon tip size
Pulse Duration(nsec)	6-8	Same
Pulse Rate [Hz]	0.5-5.0	Same

Substantial Equivalent Discussion:

The physical components of the M22 System and handpieces were unchanged compared to the legally marketed predicate device. The handpieces remain unchanged, except for the addition of several accessories and features.

The IPL Handpiece accessories that have been added have the same wavelength, pulse rate, use of sequential pulsing, and use of sapphire cooling. The expected fluence with use of the additional filters and light guides showed lower fluence than that of previously cleared devices. The higher 56J/cm^2 is supported by Lumenis 510(k) number K020839.

The Q-Switched Nd:YAG Handpiece two new treatment tips sizes have the same wavelength, pulse rate, pulse duration, and maximum fluence. The expected fluence with use of new tips showed lower fluence than that of the previously cleared device.

The ResurFX Handpiece addition of various treatment shapes and the new Precision Tip have the same wavelength, max energy per pulse and treatment tip width.

All features of the predicate and subject device were validated to work as intended within V&V activities.

Performance Bench Testing:

Performance testing was conducted in order to demonstrate the performance of the M22 System and its substantial equivalence, with respect to the safety and effectiveness of the cleared predicate device. The following activities were performed:

- Risk analysis activities in compliance with the requirements of ISO 14971.
- Electrical safety and electromagnetic compatibility testing as required to conform with the following performance standards:
  - IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
  - 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.

- IPL compatibility testing as required to conform with the following performance standard:
    - IEC 60601-2-57 Medical Electrical Equipment - Part 2-57: Particular Requirements For The Basic Safety And Essential Performance Of Non-Laser Light Source Equipment.
- Verification and validation testing:
    - All software changes have been validated to work as intended.
    - The Handpiece accessories and features that have been added were validated.

Conclusions:

Test results indicated that the subject M22 System performs in accordance with its requirements and specifications, in similarity to its predicate device. Consequently, the M22 System was found to perform as well as its predicate, to be as safe and effective for its intended use as its predicate, and is substantially equivalent to its predicate device without raising any new safety and/or effectiveness issues.

ResurFX System

Indications for Use:

The ResurFX System with wavelength of 1565 nm, is indicated for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.

Device Description:

The ResurFX System is an advanced computer-controlled laser emission system operating at a wavelength of 1565 nm, and is intended for Fractional Non-Ablative Skin Resurfacing application when using a dedicated handpiece.

The following accessories are provided with and/or may be purchased independently for the ResurFX System:

- Two (2) different treatment tips: SapphireCool and Precision tips.
- Footswitch.

Technological Characteristics and Substantial Equivalence:

This ResurFX module (K130028, K142860) was modified to be a standalone system to provide an additional member of the growing product family to meet customer needs.

The intended use and indications for use of the ResurFX System are the same as the selected predicate devices. In addition, the same technological characteristics and principles of operation apply for the ResurFX System and the predicate devices.

Comparison table of technological characteristics of the Lumenis ResurFX System compared to those of the predicate devices is provided below. The new accessories and features are bolded.

	ResurFX Module (K130028, K142860) (Predicate Devices)	**ResurFX System (Subject) (Subject Device)**
Operational Wavelengths	1565nm	Same
Max Energy	up to 70mJ per micro- beam	up to **40** or 70mJ per micro- beam, upon tip
Type of laser	Er:Glass Fiber-laser with scanner	Same
Tips	SapphireCool	SapphireCool, **Precision**
Spot size, mm	5-18	Same
Tip treatment width	18mm	Same
Scanner	Dual axis scanner	Same
Scanning shapes	Line, square, rectangle, circle, donut, hexagon	Line, square, rectangle, circle, donut, hexagon, **vertical line and vertical rectangle**
Input Power	100-240 VAC 12Amax, 50/60Hz	100-240 VAC, 3A, 50/60 Hz

Substantial Equivalent Discussion:

The standalone ResurFX module was modified to be a standalone system. The ResurFX handpieces remain unchanged, except for the addition of an accessory and feature.

The ResurFX Handpiece addition of various treatment scanning shapes and the new Precision Tip have the same wavelength, max energy per pulse, and treatment tip width.

All features of the predicate and subject device were validated to work as intended within V&V activities.

Performance Bench Testing:

Performance testing was conducted in order to demonstrate the performance of the ResurFX System and its substantial equivalence, with respect to the safety and effectiveness of the cleared predicate devices. The following activities were performed:

- Risk analysis activities in compliance with the requirements of ISO 14971.
- Electrical safety and electromagnetic compatibility testing as required to conform with the following performance standards:
  - IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
  - 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.
- Verification and validation testing:
  - All software changes have been validated to work as intended.
  - The ResurFX Handpiece added treatment shapes and the Precision Tip were validated. The wavelength, max energy per pulse, type of laser, and treatment tip width remain unchanged. The expected fluence with use of the new scan shapes and Precision tip showed same or lower fluence than that of previously cleared devices.
- Environmental testing demonstrating the ability of the subject device to withstand variant operation, storage and transportation conditions.

Conclusions:

Test results indicated that the subject ResurFX System performs in accordance with its requirements and specifications, in similarity to its predicate devices. Consequently, the ResurFX System was found to perform as well as its predicates, to be as safe and effective for its intended use as its predicate, and is substantially equivalent to its predicate device without raising any new safety and/or effectiveness issues.