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

January 21, 2015

Lumenis Limited
Ms. Elissa Burg
Director of Quality Assurance/Quality Systems
6 Hakidma Street
Yokneam 20692
Israel

Re: K142860
Trade/Device Name: Lumenis M22 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 22, 2014
Received: December 24, 2014

Dear Ms. Burg:

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″ (21CFR 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 yours,

David Krause -S

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 below.

510(k) Number *(if known)*
K142860

Device Name
Lumenis M22™ System

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:

1. The Intense Pulsed Light (IPL) handpiece with a spectrum of 400-1200nm (with 8 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)

2. 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

3. ResurFX module and handpiece, with wavelength of 1565 nm, is indicated for:
• Use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue

4. 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 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 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 2- 510(k) Summary

510(K) SUMMARY

Lumenis M22 System

510(k) Number K_____

Applicant Name: Lumenis Ltd.
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Contact Person: Elissa Burg
Director of Regulatory Affairs & Quality Systems
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E-mail: Elissa.Burg@lumenis.com

Trade Name: ***Lumenis M22™ System***

Summary Preparation Date: October 13, 2014

Classification: **Name**: Intense Pulsed Light & Laser System and delivery devices
Product Code: GEX, ONF, ONG
Regulation No: 21 CFR 878.4810
Class: II
Classification Panel: General and Plastic Surgery

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 (K083733)
- Multi-Spot Nd:YAG laser handpiece (K083733)
- ResurFX non-ablative laser handpiece (K130028)
- Q-Switched Nd:YAG laser handpiece (K043173)

Intended Use Statement:

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:

1. The Intense Pulsed Light (IPL) handpiece with a spectrum of 400-1200nm (with 8 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)

2. 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

3. **ResurFX module and handpiece, with wavelength of 1565 nm, is indicated for:**
   - Use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue

4. **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 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 regime.

Predicate Devices:

Substantial equivalence to the following predicate devices is claimed:

Device Name	510k No	Date of Clearance
Lumenis Lum One	K060448	July 5, 2006
Lumenis LUME 2	K083733	May 04, 2009
Lumenis ResurFX laser Module	K130028	Sep 03, 2013
Lumenis Quantum Q switched Nd:YAG	K043173	Jan 1, 2005
Palomar LuxV	K040081	April 1, 2004
Candela Nd:YAG laser System	K063074	Dec 27, 2006

Substantial Equivalence to Predicate Devices

The subject ***Lumenis M22 System***'s IPL handpiece uses a spectrum of 400-1200 nm, combined by filters used in Lumenis One (K060448), Lumenis LUME 2 (K083733) and Palomar LuxV (K040081)**.** The device contains filters for different parts of this spectrum, same as the predicates. The minor differences in technical specifications do not raise any new questions of safety and efficacy.

Lumenis M22 System also has the Acne filter (Notch filter 400-600 & 800-1,200 nm) for the treatment of inflammatory Acne vulgaris which is similar to the Palomar LuxV (K040081) Acne filter which has a wavelength of 400-700 nm & 870-1200 nm. The minor differences in the wavelengths do not raise any new questions of safety and efficacy.

The subject ***Lumenis M22*** system's **Multi-Spot** Nd:YAG handpiece uses a 1064nm laser, which is equivalent to the handpiece used by its predicate device: Lumenis Lume 2 (K083733). Both products use a Xenon flash-lamp pumped solid state Nd:YAG, and both utilize the same pulse rate and similar performance characteristics. The Lumenis M22 Nd:YAG laser has an additional tip of 1.5 mm, which has similar characteristics as the predicate device of Candela Nd:YAG laser system (K063074).

The subject ***Lumenis M22 System***'s ResurFX handpiece is the same as the ResurFX handpiece that was cleared under K130028 and used with the market cleared Lumenis Lume 2 (K083733), being the case for all their physical parameters as well as their intended uses.

The subject ***Lumenis M22 System***'s Q-Switched handpiece is equivalent to the Q-Switched handpiece that has been used with the market cleared Lumenis Quantum (K043173). The only differences are a minor increase in fluence (<10%), caused by the specification of the Nd:YAG rods and an additional 6mm metal tip.

Performance Standards:

The subject ***Lumenis M22 System*** complies with

- ***IEC 60601-1: 2005*** Medical Electrical Equipment-Part 1: General Requirements for Safety. Collateral Standard: Safety Requirements for Medical Electrical Systems.

- ***IEC 60601-1-2:2007*** Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
- ***IEC 60601-2-22:2007*** - Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

- ***IEC 60825-1:2007*** - Safety of laser products - Part 1: Equipment classification, and requirements.

- ***IEC 60601-2-57:2011*** - Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetics.

Performance Bench Tests

Bench testing demonstrated that the subject ***Lumenis M22 System*** is as safe and effective as the cleared predicate devices.

Summary of Pre-Clinical and Clinical Study

The safety and efficacy of all the identified handpieces applied within the subject ***Lumenis M22 System*** are well established in scientific research and clinical studies. Multiple studies with these and similar systems have shown safety in aesthetic and dermatological procedures, in addition to the devices cleared for marketing by the FDA.