DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 28, 2017

Lumenis Ltd.
Naama Jacoby
Head of Regulatory Affairs Ophthalmic Platform
6 Hakidma Street
PO Box 240
Yokneam Industrial Park
Yokneam, IL 2069204

Re: K162837
Trade/Device Name:
Smart Laser Indirect Ophthalmoscope (LIO); Laser delivery device for Lumenis Novus Spectra Laser System, Lumenis Vision One Laser System, and Lumenis Smart532™ 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
Dated: January 22, 2017
Received: January 24, 2017

Dear Ms. 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 yours,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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)*
K162837

Device Name
Smart Laser Indirect Ophthalmoscope (LIO); Laser delivery device for Lumenis Novus Spectra Laser System, Lumenis Vision One Laser System, and Lumenis Smart532™ Laser System

Indications for Use *(Describe)*
The Lumenis Smart Laser Indirect Ophthalmoscope (LIO) is a battery-powered optical instrument intended for the viewing of the posterior segment of the eye and to deliver laser energy for photocoagulation procedures on the peripheral retina of the eye (in conjunction with the use of a hand-held condensing lens).

The Smart LIO is indicated for use in the following photocoagulation procedures:
- Panretinal photocoagulation;
- Segmental peripheral photocoagulation;
- Retinopexy; and,
- Pediatric retinal repairs (under general anesthesia).

The Smart LIO is intended to work in conjunction with the following Lumenis laser systems in ophthalmic photocoagulation procedures:
- Lumenis Novus Spectra Laser System;
- Lumenis Vision One Laser System; and
- Lumenis Smart532™ Laser System.

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

Smart Laser Indirect Ophthalmoscope (LIO);

Laser delivery device for Lumenis Novus Spectra Laser System, Lumenis Vision One Laser System, and Lumenis Smart532™ Laser System

Date Prepared:	February 26th, 2016
Applicant Name and Address:	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 Regulatory Affairs Ophthalmic Platform Lumenis Ltd. Tel: +972-4-9599085 Fax: +972-4-9599198 Mail: Naama.Jacoby@lumenis.com
Trade Name:	Smart Laser Indirect Ophthalmoscope (LIO); Laser delivery device for Lumenis Novus Spectra Laser System, Lumenis Vision One Laser System, and Lumenis Smart532™ Laser System
Common Name:	Laser Indirect Ophthalmoscope (LIO)
Classification Name:	Powered laser surgical instrument
Product Code:	GEX
Device Class:	Class II
Regulation Number:	21 CFR 878.4810
Panel:	General & Plastic Surgery
Predicate Device:	Laser Indirect Ophthalmoscope, Keeler model, cleared under K022181.
Reference Devices:	Keeler Vantage Plus Binocular Indirect Ophthalmoscope cleared under K060822, Lumenis Smart532™ Laser System cleared under K151109, Lumenis Vision One Laser Systems, cleared under K111213 and Lumenis Novus Spectra Laser System cleared under K022327

Intended Use/ Indications for Use:

The Lumenis Smart Laser Indirect Ophthalmoscope (LIO) is a battery-powered optical instrument intended for the viewing of the posterior segment of the eye and to deliver laser energy for photocoagulation procedures on the peripheral retina of the eye (in conjunction with the use of a hand-held condensing lens).

The Smart LIO is indicated for use in the following photocoagulation procedures:

- Panretinal photocoagulation;
- Segmental peripheral photocoagulation;
- Retinopexy; and,
- Pediatric retinal repairs (under general anesthesia).

The Smart LIO is intended to work in conjunction with the following Lumenis laser systems in ophthalmic photocoagulation procedures:

- Lumenis Novus Spectra Laser System;
- Lumenis Vision One Laser System; and
- Lumenis Smart532™ Laser System.

Modified Device Description:

The Lumenis Smart Laser Indirect Ophthalmoscope (LIO) is a battery-powered optical instrument intended for the viewing of the posterior segment of the eye and to deliver laser energy for photocoagulation procedures on the peripheral retina of the eye (in conjunction with the use of a hand-held condensing lens). The Smart LIO is used in conjunction with a compatible Lumenis ophthalmic laser systems. The LIO illuminates and magnifies the fundus image for observation, and when connected to a Lumenis ophthalmic laser system, the laser aiming and treatment beams are precisely focused and delivered to the patient’s eye through the LIO.

The Smart LIO is a wireless headset worn on the physician's head and is used to treat patients in a supine position or who could not otherwise be treated using a standard slit lamp delivery system.

Technological Characteristics and Substantial Equivalence

The intended use and indications for use of the Smart LIO are the same as the selected predicate devices. In addition, the same technological characteristics and principles of operation apply for the Smart LIO and the predicate device. The modifications introduced to the subject Smart LIO as compared to the predicate device are designed and intended mainly for increased user convenience.

Comparison table of technological characteristics of the Smart LIO compared to those of the predicate device is provided below:

Parameter	**Lumenis LIO, Keeler model (K022181) (Predicate Device)**	**Lumenis Smart LIO (Subject device)**
LIO Headset	Keeler, Fison model	Keeler, Vantage Plus model (K060822)
Lumenis Laser System Compatibility	• Smart532 (K151109) • Vision One (K111213) • Novus Spectra (K022327) • Novus Varia, • Novus Verdi, • Novus Omni, • Novus 2000, • Ultima & Ulima SE,	• Smart532 (K151109) • Vision One (K111213) • Novus Spectra (K022327)
Laser Source & Wavelengths Compatibility: • Laser Source: • Treatment beam: • Aiming beam:	Nd:YAG, Argon, Krypton 532, 561, 659 nm 635nm	Nd:YAG, DPSS, Nd:GdVO4 532, 577, 659 nm 635nm
Spot Sizes, at LIO focal plane	910 µm± 10%	1100 µm± 20%
Working distance:	366 mm (14.41")	280mm (11.02”)
Eye Safety Filter	Fixed, blocking treatment wavelengths, OD>5	Fixed, blocking treatment wavelengths, OD>5
Transmission:	>70%	>70%
Optical Fiber Length	4.6 meters	5 meters
Illumination source	Xenon Bulb	LED
Dimensions (HxWxL): • **Headset** • **Power Supply / Charging Station**	17.7cm x 20.3cm x 40.6cm 26.1cm x 23.1cm x 36cm	18.0-22.0cm× 25.0cm × 30.0-38.0cm 12.0cm x 18.4cm x 20.7cm
Weight: • **Headset** • **Power Supply / Charging Station**	545 grams (1.2lbs) 5.44 Kg (12 lbs)	800 grams (1.87 lbs) 0.4 Kg
Electrical Requirements	Power Supply; • Voltage: 120/230V AC±l0%; • Frequency:50/60Hz • Current: 0.8 Amp max	Charging Station; • Voltage: 100-240V AC, • Frequency: 50/60Hz, • Current: 0.7 Amp max

Performance testing was conducted in order to demonstrate the performance of the Smart LIO 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.
- Light hazard protection compatibility testing as required to conform with the following performance standard:
  - ISO 15004-2 Ophthalmic Instruments - Fundamental requirements and test methods Part 2: Light hazard protection
- Verification and validation testing:
  - The binocular viewing optics and illumination controls of the Binocular Indirect Ophthalmoscope (by Keeler Instruments, Inc within their cleared device).
  - The modification of the laser delivery optics were verified and confirmed the Smart LIO:
    - Laser beam emission test for all laser wavelengths,
    - Laser spot size test at working distance of 280mm for all wavelengths
    - Aiming beam transmission testing through the Smart LIO.
  - Eye safety filters transmission test; performed at laser treatment wavelengths of 532nm, 577nm, 659 nm and aiming beam wavelength of 635nm
  - Smart LIO communication to laser systems test; test preformed for all compatible laser systems for all connection modes.
- Environmental testing demonstrating the ability of the subject device to withstand variant operation, storage and transportation conditions.

Test results indicated that the subject Smart LIO performs in accordance with its requirements and specifications, in similarity to its predicate device. Consequently, the Smart LIO 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.