DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 30, 2015

Lumenis Incorporated
Mr. Rick Gaykowski
Global Vice President, Regulatory Affairs & Quality Systems
1870 South Milestone Drive
Salt Lake City, Utah 84101

Re: K151109
Trade/Device Name: Lumenis® Smart532™ Laser System and accessories
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: August 20, 2015
Received: August 27, 2015

Dear Mr. Gaykowski:

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 Parts 801 and 809); 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,

Joshua C. Nipper -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)*
K151109

Device Name
Lumenis® Smart532™ Laser System and accessories

Indications for Use *(Describe)*
The Lumenis® Smart532™ Laser System is indicated for use in Ophthalmic Applications; Ear, Nose and Throat Applications; Dentistry; and Dermatologic Applications as follows:

Ophthalmology
Diabetic Retinopathy including Macular Edema or Proliferative Retinopathy
Proliferative Diabetic Retinopathy (PDR)
Retinal Tear
Macular Edema or Proliferative Retinopathy associated with Central Retinal Vein Occlusion (CRVO) or Branch Retinal Vein Occlusion (BRVO)
Choroidal Neovascularization (CNV) secondary to Age-related Macular Degeneration (AMD)
Central Serous Chorioretinopathy (CSCR)
Trabeculoplasty for Primary Open Angle Glaucoma (POAG)
Iridotomy / Iridoplasty for Angle-Closure Glaucoma (ACG)

Ear, Nose and Throat (ENT)
Stapedectomy
Stapedotomy
Myringotomies
Lysis of Adhesions
Control of Bleeding
Removal of Acoustic Neuromas
Soft Tissue Adhesion in Micro/Macro Otologic procedures

Dermatology
Pigmented lesion, including soar lentigine
Vascular lesions, including cherry hemangiomas and angiokeratomas
Extremeties telangiectases, including facial and leg telangiectases
Cutaneous lesions
Flat warts
Dermatosis
Papulosa Nigra

Dentistry
Frenectomy
Treatment of oral mucous cyst
Treatment of benign vascular lesions:
- Capillary hemangioma
- Hemorrhagic hereditary telangiectasia
- Capillary/cavernous hemangiomas
- Lymphangioma
- AV malformation of the tongue
- Hermaniolymphangiomas

Photocoagulation of superficial vessels

Vaporization of superficial blood or lymph containing vessels
Treatment of superficial tongue lesions
Tissue management and hemostasis for crown and bridge impressions
Incision and drainage for abscess
Gingivoplasty/Gingivectomy:
- Operative procedures
- Crown and bridge, gingival reduction
- Crown lengthening

Hyperplasia (Drug, irritation, Epulus, ...)
Hemostasis during dental procedures
Operculectomy (Operculotomy)
Excisional biopsy
Free Ginvical Graft (Adjunct):
- Hemostasis of donor site
- Hemostasis of graft site

Vestibuloplasty
Soften Gutta Percha
Treatment of canker sores, herpetic lesions, and aphthous ulcers
Laser-assisted bleaching/whitening

Device energy delivery options:

Energy Delivery Option	Indication
SmartPulse	Diabetic Retinopathy including Macular Edema or Proliferative Retinopathy, Proliferative Diabetic Retinopathy (PDR), Central Serous Chorioretinopathy (CSCR), Macular Edema or Proliferative Retinopathy associated with Branch Retinal Vein Occlusion (BRVO)
CW (Continuous Wave)	All Indications

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Lumenis Smart532™ Laser System

510(K) Summary

I. Submitter General Information:

Device Owner Name:	Lumenis, Inc.
Address:	1870 S Milestone Dr
	Salt Lake City, UT 84104
Contact:	Jace R. McLane
Phone:	801-656-2328
Fax:	801-656-2415
Date of Preparation:	18 September, 2015

II. Device Name:

Trade Name:	Lumenis® Smart532™ Laser System
Common/Usual Name(s):	Surgical Laser
Class:	Class II
Classification Name(s):	79 GEX, Laser Instrument, Surgical Powered
CFR Reference:	21 CFR § 878.4810, Laser surgical instrument for use in general and plastic surgery and in dermatology

III. Predicate Device Name(s):

Trade Name(s):	Lumenis® Novus Spectra™ Laser System (K022327)
	Iridex® IQ 532 Laser System (K071687)

IV. Device Description:

The subject Lumenis® Smart532™ Laser System product is a dual port, solid state, frequency doubled, green Nd:GdVO4 surgical laser instrument used in the photothermolysis (photocoagulation) of soft tissue at an operating emission wavelength of 532nm, a wavelength that has been used widely and effectively in the market for procedures in the fields of ophthalmology, ENT (ear, nose & throat), dermatology and dentistry.

Compatible delivery devices & accessories for use with the subject Lumenis® Smart532™ Laser System include: Slit lamps, Slit lamp adapters/attachments, Laser Indirect Ophthalmoscopes (LIO), Eye safety filters, Laser links, Array LaserLink, Selecta Trio, Fibers and Endo-ocular and Endo-Oto probes. The device software may be adjusted by Lumenis to fit customer needs within the system overall range of parameters.

V. Intended Use:

The subject Lumenis® Smart532™ Laser System delivery device is indicated for a variety of uses, identical to unaltered indications from the primary predicate Lumenis® Novus Spectra™ Laser System (K022327), to direct indications enumerated within the product Operator Manual, as follows:

The Lumenis Smart532™ Laser System is indicated for use in Ophthalmic Applications; Ear, Nose and Throat Applications; Dentistry; and Dermatologic Applications as follows:

Ophthalmology
Diabetic Retinopathy including Macular Edema or Proliferative Retinopathy
Proliferative Diabetic Retinopathy (PDR)
Retinal Tear
Macular Edema or Proliferative Retinopathy associated with Central Retinal Vein Occlusion (CRVO) or Branch Retinal Vein Occlusion (BRVO).
Choroidal Neovascularization (CNV) secondary to Age-related Macular Degeneration (AMD)
Central Serous Chorioretinopathy (CSCR)
Trabeculoplasty for Primary Open Angle Glaucoma (POAG)
Iridotomy / Iridoplasty for Angle-Closure Glaucoma (ACG)

Ear, Nose and Throat (ENT)
Stapedectomy
Stapedotomy
Myringotomies
Lysis of Adhesions
Control of Bleeding
Removal of Acoustic Neuromas
Soft Tissue Adhesion in Micro/Macro Otologic procedures

Dermatology
Pigmented lesion, including soar lentigine
Vascular lesions, including cherry hemangiomas and angiokeratomas
Extremeties telangiectases, including facial and leg telangiectases
Cutaneous lesions
Flat warts
Dermatosis
Papulosa Nigra

Dentistry
Frenectomy
Treatment of oral mucous cyst
Treatment of benign vascular lesions
- Capillary hemangioma
- Hemorrhagic hereditary telangiectasia
- Capillary/cavernous hemangiomas
- Lymphangioma
- AV malformation of the tongue
- Hemangiolymphangiomas

Photocoagulation of superficial vessels
Vaporization of superficial blood or lymph containing vessels
Treatment of superficial tongue lesions
Tissue management and hemostasis for crown and bridge impressions
Incision and drainage for abscess
Gingivoplasty/Gingivectomy
- Operative procedures
- Crown and bridge, gingival reduction
- Crown lengthening

Hyperplasia (Drug, irritation, Epulus…)

Hemostasis during dental procedures
Operculectomy (Operculotomy)
Excisional biopsy
Free Ginvical Graft (Adjunct):

- Hemostasis of donor site
- Hemostasis of graft site

Vestibuloplasty
Soften Gutta Percha
Treatment of canker sores, herpetic lesions, and aphthous ulcers
Laser-assisted bleaching/whitening

Device energy delivery options

Energy Delivery Option	**Indication**
SmartPulse	Diabetic Retinopathy including Macular Edema or Proliferative Retinopathy, Proliferative Diabetic Retinopathy (PDR), Central Serous Chorioretinopathy (CSCR), Macular Edema or Proliferative Retinopathy associated with Branch Retinal Vein Occlusion (BRVO)
CW (Continuous Wave)	All Indications

VI. Substantial Equivalence Discussion:

The subject Lumenis® Smart532™ and primary predicate Lumenis® Novus Spectra™ Laser System (K022327) are based on a diode pumped solid state frequency doubled laser.

Both subject and predicate(s) devices' laser systems (Lumenis® Novus Spectra Laser System (K022327) and Iridex® IQ 532 Laser System (K071687)) share the same 532 nm output, a wavelength that has been used widely and effectively in the market for procedures in the fields of ophthalmology, ENT (ear, nose & throat), dermatology and dentistry. The Iridex IQ 532 Laser System (K071687) is not cleared for any dentistry indications. The outputs of both systems' laser sources also share the same power range characteristics.

Additional design changes such as dual port, addition of touch screen etc., did not raise new questions of safety and effectiveness and did not alter the basic fundamental scientific technology of the device.

The subject device, Lumenis® Smart532 Laser System and primary predicate Lumenis® Novus Spectra Laser System (K022327) do not share the SmartPulse (train of brief pulses) energy delivery method. However, the Iridex® IQ 532 Laser System secondary predicate (K071687) does include a MicroPulse (spaced, single and repetitive train of brief pulses) energy delivery method, which is similar in terms of temporal ranges to the SmartPulse of the subject device and establishes substantial equivalence as shown in the table below:

Characteristics	Subject Device – Lumenis® Smart532™ Laser System	Primary Predicate Device – Lumenis® Novus Spectra™ Laser System (K022327)	Secondary Predicate Device – Iridex® IQ 532 Laser System (K071687)
Indications for Use	Ophthalmic, ENT, Dermatology, & Dentistry	Ophthalmic, ENT, Dermatology, & Dentistry (See K022327)	Dermatology, ENT/otolaryngology, & Ophthalmic (See K071687)
Treatment wavelength	532nm	532nm	532nm
Aiming beam	Diode, 635nm	Diode, 635nm	Diode, 635nm
Laser Type	Diode Pumped Solid State (frequency doubled)	Diode Pumped Solid State (frequency doubled)	Diode, Diode-pumped, frequency doubled, solid state
Power Input	100-240 VAC	100-240 VAC	100-240 VAC
Power Output	50-2,500mW (nominal)	50-1,500mW 50-2,500mW	0-2,500mW
Operating mode	Single Pulse, CW (Continuous Wave), SmartPulse	Single Pulse, CW (Continuous Wave)	CW(CW-Pulse, MicroPulse, Long Pulse
Pulse duration	Single Pulse CW: 5 – 3,000msec SmartPulse: 0.05-1.00msec	Single Pulse, CW: 10-3,000msec	CW: 10-3,000msec MicroPulse: 0.05-1.00msec
Pulse/Exposure interval	CW: 10-1,500msec SmartPulse: 0.5-10msec	CW: 50-1,000msec	CW: 10-3,000msec MicroPulse: 1.00 – 10.00msec
Display Type and User Interface	Color display panel w/Touchscreen & pushbutton selectors	Monochromatic seven segment indicators and pushbutton selectors	Color Graphic Touchscreen manual/Remote Controls

Table 1: 510(k) Summary Device Comparison Table

VII. Performance Data:

Appropriate testing for the subject Smart532™ Laser System device, including safety, performance and functional testing, has been performed to determine substantial equivalence to the predicate devices Lumenis® Novus Spectra™ Laser System and Iridex® IQ 532 Laser System .

The subject Lumenis® Smart532™ Laser System product has been subjected to outside independent laboratory testing regarding electrical safety & EMC requirements per governing

IEC 60601 3rd-Edition Series, and side-by-side comparative performance assessment to the identified primary predicate Lumenis® Novus Spectra™ Laser System (K022327). The subject product has undergone verification & validation protocol controlled examination testing to ensure the subject product met all determined design specifications and was determined as substantially equivalent. As a result, Lumenis maintains that all established testing criteria and product performance specifications have been met, demonstrating that equivalent indications for use, safety compliance, similar design features, functional characteristics, fundamental technology features, technical applications, patient population, and general modes of operation of the subject device are indeed substantially equivalent to cited predicate devices.

Based on the indications for use, technological characteristics, safety and performance testing, the subject Lumenis® Smart532™ Laser System product meets the requirements considered adequate for its intended use and is substantially equivalent in design, materials, technical features, treatment population, principles of operation and indications for use to current commercially available cited predicates.

VIII. Conclusion:

The Lumenis® Smart532™ Laser System subject device has equivalent intended use, general design, and fundamental scientific technology as the predicate devices: Lumenis® Novus Spectra™ Laser System (K022327) and the Iridex® IQ 532 Laser System (K071687). There are no new hazards introduced by the Lumenis® Smart532™ Laser System subject device as compared with the cited predicate devices.