5. 510(k) SUMMARY

510(k) Summary

JUL 25 2011

I. Submitter General Information:

Device Owner Name:	Lumenis, Inc.
Address:	3959 West 1820 South Salt Lake City, UT 84104
Contact:	Jace R. McLane
Phone:	801-656-2328
Fax:	801-656-2627
Date of Preparation:	April 29, 2011

II. Device Name:

Trade Name:	Vision One Laser System
Common/Usual Name(s):	Surgical Laser, Ophthalmic Laser
Class:	Class II
Classification Name(s):	79 GEX, Laser Powered Surgical Instrument 86 HQF, Laser, Ophthalmic
CFR Reference:	21 CFR § 878.4810, Laser surgical instrument for use in general and plastic surgery and in dermatology 21 CFR § 886.4390, Ophthalmic Laser

III. Predicate Device Name(s):

Trade Name(s): Novus Varia Laser System (K022181)

IV. Device Description:

The Vision One Laser System is classified as a Class IV laser by the Center for Devices and Radiological Health of the Food and Drug Administration. The Vision One Laser System is intended for use in the treatment of ocular pathology. The system's green, yellow, and red wavelengths are indicated for use in photocoagulation of both anterior and posterior segments. The Vision One Laser System will incorporate the newest laser technology - Optically Pumped Semiconductor Laser (OPSL) in additions to Nd:YAG which are both subsets of DPSS (Diode Pumped Solid State Laser).

The system shall be configurable so that any combination of up to three (3) treatment lasers can be installed and used.

The Vision One Laser System is comprised of the laser console, control and display panel, remote control, an external door interlock plug, & footswitch.

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The following accessories & delivery devices are compatible and available for the Vision One Laser System:

Lumenis 1000 Integrated Slit Lamp, Lumenis InSight Integrated Slit Lamp, LaserLinks: SL130 Zeiss Slit Lamp, 30SL Zeiss Slit Lamp, 20SL Zeiss Slit Lamp, 125SL Zeiss Slit Lamp, Haag Streit Slit Lamp, Lumenis LaserLink S, Eye Safety Filter for all LaserLinks listed, Single and Dual Endo Kits for Zeiss and Leica / Wild microscopes, Endo Kit for Leica M840, Keeler LIO (Laser Indirect Ophthalmoscope), & Heine LIO (Laser Indirect Ophthalmoscope).

The Vision One Laser System uses the same types of delivery devices and accessories as the predicate device.

V. Intended Use:

The Vision One Laser System is intended for use in the treatment of ocular pathology. The Vision One Laser System green, yellow, and red wavelengths are indicated for use in photocoagulation of both anterior and posterior segments including:

- Retinal photocoagulation, panretinal photocoagulation, and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroid including:
  - Proliferative and nonproliferative diabetic retinopathy
  - Choroidal neovascularization
  - Branch retinal vein occlusion
  - Retinal tears and detachments
  - Retinopathy of prematurity
- Iridotomy, iridectomy, and trabeculoplasty in angle closure glaucoma and open angle glaucoma

VI. Substantial Equivalence Summary:

The Vision One Laser System has the same intended use as the predicate device - Novus Varia Ophthalmic Laser (K022181). It uses the same fundamental scientific technology as the predicate device. In addition, Vision One Laser System and the predicate device have the same patient population, principles of operation, method of energy delivery, critical materials, and basal design.

VII. Performance Data:

The appropriate testing, including safety, performance and functional testing, to determine substantial equivalence has been conducted.

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VIII. Conclusion:

The subject device, the Vision One Laser System, has the same intended use, general design, and fundamental scientific technology as the predicate device (K022181).

The Vision One Laser System uses technology substantially equivalent to the Novus Varia Ophthalmic Laser (K022181). There are no new hazards introduced by the Vision One Laser System as compared with the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Lumenis, Inc.
% Ms. Jace R. McLane
3959 West 1820 South
Regulatory Affairs Specialist
Salt Lake City, Utah 84104

JUL 25 2011

Re: K111213
Trade/Device Name: Vision One 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: July 15, 2011
Received: July 18, 2011

Dear Ms. McLane:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Erin J Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

LUMENIS®
Enhancing Life. Advancing Technology.

4. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K111213

Device Name: Vision One Laser System

Indications for Use:

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  - Retinal tears and detachments
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- Iridotomy, iridectomy, and trabeculoplasty in angle closure glaucoma and open angle glaucoma

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Neil R. Ogden for mm
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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