5. 510(k) SUMMARY

510(k) Summary

NOV 0 1 2013

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:	801-656-2415
Date of Preparation:	March 1, 2013

II. Device Name:

Trade Name:	Lumenis® Array™ LaserLink™
Common/Usual Name(s):	Surgical Laser
Class:	Class II
Classification Name(s):	HQF, Laser, Ophthalmic
CFR Reference:	21 CFR § 886.4390, Ophthalmic Laser

III. Predicate Device Name(s):

Trade Name(s): Nidek Multicolor Scan Laser Photocoagulator MC-500 Vixi (#K111493).

Topcon PASCAL Streamline 577 (#K111108)

Topcon (OptiMedica) PASCAL Streamline Photocoagulator (#K100019)

Lumenis Vision One Laser System (#K111213)

IV. Device Description:

The Lumenis® Array™ LaserLink™ device is a delivery system that adapts an examination slit lamp for use as a therapeutic laser delivery system, utilizing a scanning pattern generator to deliver predefined patterns of treatment.

The Lumenis® Array™ LaserLink™ device is comprised of the following components:

- Array™ LaserLink™ module
- Console
- Touchscreen display
- Remote touchpad

The Array™ LaserLink™ module attaches to the slit lamp and delivers the treatment beam to the target tissue.

The console houses the control electronics and power supply, and integrates the Array™ LaserLink™ module with the laser system.

The touchscreen display is used to adjust laser treatment settings, such as laser mode, energy, and aiming beam intensity. It can be positioned on either side of the slit lamp, and duplicates the functions of the laser's remote control.

The touchpad is used to micromanipulate the position of the aiming and treatment beams, adjust laser power, spot size, the number of spots, and pattern parameters.

V. **Intended Use:**

Device Name: Lumenis® Array™ LaserLink™

Indications for Use:

The Lumenis® Array™ LaserLink™ device is a laser system accessory intended for use in the treatment of ocular pathology.

- For the posterior segment, the Lumenis® Array™ LaserLink™ device is indicated for use in retinal photocoagulation and panretinal photocoagulation of vascular and structural abnormalities of the retina and choroid including:
  - o Proliferative and severe and very severe nonproliferative diabetic retinopathy
  - o Macular edema associated with proliferative or nonproliferative diabetic retinopathy
  - o Choroidal neovascularization
  - o Retinal neovascularization associated with retinal occlusive disease (Branch retinal vein occlusion; Central retinal vein occlusion)
  - o Macular edema associated with Branch retinal vein occlusion
  - o Retinal tears and detachments
- And anterior segments as follows:
  - o Iridotomy in closed angle glaucoma
  - o Trabeculoplasty in open angle glaucoma

The Lumenis Laser Systems compatible for connection with the Lumenis® Array™ LaserLink™ device are:

- Novus Spectra™ Laser System (K022327)(532nm)
- Novus Spectra™ Dual Port Laser System (K022327)(532nm)
- Vision One™ Laser System (K111213)(532nm, 577nm, 659nm)

Table 2 Pattern Indications For Use

Condition	Treatment	Pattern Selection Option	Specific Pattern
Posterior segment: Retina			
Proliferative Diabetic Retinopathy	Panretinal Photocoagulation	Yes	All patterns except circle/half circle arc

Severe and Very Severe Non-Proliferative Diabetic Retinopathy	Panretinal Photocoagulation	Yes	All patterns except circle/half circle arc
Macular Edema associated with Proliferative or Non-Proliferative Diabetic Retinopathy	Focal Photocoagulation	No	Single Spot (no pattern)
	Grid Photocoagulation	Yes	Square, arc, line
Retinal neovascularization associated with Retinal Occlusive Disease (Branch Retinal Vein Occlusion; Central Retinal Vein Occlusion)	Panretinal Photocoagulation	Yes	All patterns except circle/half circle arc
Macular Edema associated with Branch Retinal Vein Occlusion	Grid Photocoagulation	Yes	Square, arc, line
Retinal Tears and Detachments	Laser Retinopexy	Yes	Circle, half circle, quarter circle
Choroidal Neovascularization	Focal Laser	No	Single Spot (no pattern)
Anterior Segment: Glaucoma			
Primary Open-Angle Glaucoma	Trabeculoplasty	No	Single Spot (no pattern)
Closed Angle Glaucoma	Iridotomy	No	Single Spot (no pattern)

VI. Substantial Equivalence Summary:

The Lumenis® Array™ LaserLink™ device has equivalent intended use as the identified predicate device – Nidek Multicolor Scan Laser Photocoagulator MC-500 Vixi (#K111493), Topcon PASCAL Streamline 577 (#K111108), Topcon (OptiMedica) PASCAL Streamline Photocoagulator (#K100019); and Lumenis Vision One Laser System (#K111213), and also employs the same fundamental scientific technology as the identified predicate devices. In addition, the subject device, Lumenis® Array™ LaserLink™, and the predicate devices service similar indications for use, equivalent principles of operation, method of energy delivery, critical materials, and basal design elements when directly compared.

Table 2 510(k) Summary Predicate Comparison

	Predicate Device	**Predicate Device**	**Predicate Device**	**Predicate Device**	**Subject Device**
Charact-eristics	**K111493 Nidek MC-500 Vixi**	**K111108 Topcon PASCAL Streamline 577**	**K100019 Topcon /OptiMedica PASCAL Streamline Photocoagulator**	**K111213 Lumenis Vision One Laser System**	**K130195 Lumenis® Array™ LaserLink™**
Treatment λ	532nm, 577nm, & 647nm	577nm	532nm	532nm, 577nm, 659nm	532nm, 577nm, & 659nm

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	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Subject Device
Charact-eristics	**K111493 Nidek MC-500 Vixi**	**K111108 Topcon PASCAL Streamline 577**	**K100019 Topcon /OptiMedica PASCAL Streamline Photocoagulator**	**K111213 Lumenis Vision One Laser System**	**K130195 Lumenis® Array™ LaserLink™**
Laser Type	Diode Pumped Solid State	OPSL – Optically Pumped Semi-conductor Laser	OPSL – Optically Pumped Semi-conductor Laser	OPSL – Optically Pumped Semi-conductor Laser	OPSL – Optically Pumped Semi-conductor Laser
Power Input	100-240 VAC	100-240 VAC	100-240 VAC	100-240 VAC	100-240 VAC
Display Type & User interface	Color LCD panel w / Touchscreen	Adjustable LCD touchscreen control panel (color)	Adjustable LCD touchscreen control panel (color)	Color LCD panel w / Touchscreen	Color LCD panel w / Touchscreen
Compatible Lasers	Integrated: Nidek MC-500: 532nm, 577nm, 647nm (Integrated)	Integrated: Topcon PASCAL Streamline 577: 577nm (Integrated)	Integrated: Topcon / OptiMedica PASCAL Streamline Photocoagu-lator: 532nm (Integrated)	Laser with Green (532nm), Yellow (577nm), & Red (659nm) wavelength Single spot delivery.	Non-Integrated: Lumenis Vision One: 532nm, 577nm, 659nm Lumenis Novus Spectra Family: 532nm

VII. Performance Data:

The appropriate testing, including safety, performance and functional testing, to determine substantial equivalence has been conducted for the subject Lumenis® Array™ LaserLink™ device. IEC Testing has been completed and reports received. The Test Reports use the colloquial name of Scanning LaserLink™ rather than the determined trade name of Array™ LaserLink™.

The subject Array™ LaserLink™ product has been subjected to outside independent laboratory testing regarding electrical safety & EMC requirements per governing IEC 60601 Series, been subjected to side-by-side comparative performance assessment to competitive products, and has undergone protocol governed verification & validation to ensure the subject product met all determined design specifications and was substantially equivalent to named predicates. As a result, Lumenis verifies that all established testing criteria and product performance specifications have been duly met, demonstrating that equivalent indications for use, safety compliance, similar design features, functional characteristics, fundamental technology features, technical applications, service similar indications for use, and general modes of operation are substantially equivalent to cited predicate devices.

Based on the indications for use, technological characteristics, and safety and performance testing, the subject Array™ LaserLink™ product meets the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, technical features, service of similar indications for use, principles of operation and indications for use to current commercially available scanners/cited predicates.

VIII. Conclusion:

The Lumenis® Array™ LaserLink™ subject device has equivalent intended use, general design, and fundamental scientific technology as the predicate devices - Nidek Multicolor Scan Laser Photocoagulator MC-500 Vixi (#K111493), Topcon PASCAL Streamline 577 (#K111108), Topcon (OptiMedica) PASCAL Streamline Photocoagulator (#K100019), and Lumenis Vision One Laser System (#K111213). There are no new hazards introduced by the Lumenis® Array™ LaserLink™ device as compared with the predicate devices.

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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

November 1, 2013

Lumenis, Incorporated
Mr. Jace R. McLane
Regulatory Affairs Specialist
3959 West 1820 South
Salt Lake City, Utah 84194

Re: K130195
Trade/Device Name: Lumenis® Array™ LaserLink™
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: October 4, 2013
Received: October 10, 2013

Dear Mr. 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.

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 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. 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,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K130195

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Macular Edema associated with Branch Retinal Vein Occlusion	Grid Photocoagulation	Yes	Square, arc, line
Retinal Tears and Detachments	Laser Retinopexy	Yes	Circle, half circle, quarter circle
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Prescription Use __XX__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Neil R Ogden
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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number _K130195_____