OCT 01 2002

K022181

Attachment 10
510(k) Summary Statement for the
Novus® Varia™ Ophthalmic Laser and Delivery Devices

I. General Information

Submitter:	Lumenis, Inc. 2400 Condensa Street Santa Clara, California, U. S. A. 95051-0901
Contact Persons:	1. Karen L. Baker 2. K. Delane Dale
Summary Preparation Date:	June 28, 2002

II. Names

Device Names:	Novus® Varia™ Ophthalmic Laser and Delivery Devices
Primary Classification Name:	

III. Predicate Devices

- Novus Omni Laser System (K932468)
- Iris Medical Oculight GL and Delivery Devices (K960971)
- Ultima 2000/Ultima 2000SE (K913127)
- Coherent System 920 Argon/Krypton Laser (K837235)
- LaserLink Z Slit Lamp Laser Delivery Adapter (LaserLink Z & LaserLink Z-1000) (K000498, K991258, K932468)
- Acculite Endophotocoagulation Probe Delivery System (K991258, K932468, K913127)
- Laser Indirect Ophthalmoscope (K991258, K932468, K913127, K885196)

IV. Product Description

The Novus Varia Laser System is an air cooled, diode-pumped, solid state, Nd:YAG, three-color laser system (green, yellow and red) intended for use in the treatment of ocular pathology. A red diode laser provides a visible aiming beam. The Novus Varia system is comprised of the following functional components: a laser console; control and display panel; system microprocessor control electronics; two fiber ports for delivery systems; eye safety filter port; a covered footswitch; operating software; an optional remote control unit; an optional printer; delivery devices with accessories

Compatible delivery devices include: the LaserLink Z and LaserLink Z-1000 Slit Lamp Delivery Adapters; the Laser Indirect Ophthalmoscope (Heine and Keeler models) and the

V. Indications for Use

The Novus Varia Ophthalmic Laser and Delivery Devices is intended for use in the treatment of ocular pathology. The NovusVaria is 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;
  - age-related macular degeneration
  - retinal tears and detachments
  - retinopathy of prematurity

- Iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma

Laser Indirect Ophthalmoscope

The Laser Indirect Ophthalmoscope is indicated for use in the following ophthalmic treatments: diabetic retinopathy (panretinal photocoagulation); retinopexy; segmental peripheral photocoagulation; segmental photocoagulation; cloudy vitreous cavities; and, pediatric retinal repairs (under general anesthesia)

Endophotocoagulation

The Acculite Endoprobe is indicated for use in the following ophthalmic applications: photocoagulation of the anterior and posterior segment, including: anterior segment treatment in the surgical management of glaucoma; endophotocoagulation in vitreoretinal surgery, including panretinal photocoagulation, retinopexy, and treatment of neovascularization.

VI. Rationale for Substantial Equivalence

The Novus Varia Ophthalmic Laser with Delivery Devices and Accessories share the same intended use, indications for use and the same or similar technological characteristics (including treatment wavelengths, laser active medium, pumping system, aiming beam, mode of operation, exposure duration, power, treatment intervals, spot sizes, controls and displays, laser energy delivery control (footswitch), and delivery systems), and therefore is substantially equivalent to the predicate devices referenced in Section III.

VII. Performance Data

System and software hazard analysis information and software verification and validation information was submitted in conjunction with this Premarket Notification submission. The determination of substantial equivalence was based upon the comparison of the technical characteristics between the Novus Varia Ophthalmic Laser with Delivery Devices and the predicate laser systems.

VIII. Conclusion

The Novus Varia Ophthalmic Laser and Delivery Devices are substantially equivalent to similar predicate laser devices, delivery systems and accessories. The Novus Varia Ophthalmic Laser and Delivery Devices share the same intended use, indications for use, and technological characteristics as the predicate ophthalmic laser systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 01 2002

Ms. Karen L. Baker
Regulatory Consultant
Lumenis, Inc.
2400 Condensa Street
Santa Clara, CA 95051-0901

Re: K022181
Trade/Device Name: Novus® Varia™ Ophthalmic Laser and Delivery Devices
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 28, 2002
Received: July 3, 2002

Dear Ms. Baker:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2
Indications for Use Statement as Requested by FDA

510(K) Number (if Known): K022181

Device Name: **Novus Varia Ophthalmic Laser and Delivery Devices**

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use: ✓
(Per 21 CFR 801.109)

Over-The-Counter Use: _____

Optional Format 1-2-96

510(k) Number K022181