OCT - 9 2003

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Attachment 10
510(k) Summary Statement for the
Novus TTx Laser and Delivery Devices

I. General Information

Submitter:	Lumenis, Inc. 2400 Condensa Street Santa Clara, California, U. S. A. 95051-0901
Contact Persons:	Karen L. Baker
Summary Preparation Date:	October 2, 2003

II. Names

Device Names:	Novus TTx Laser and Delivery Devices
Primary Classification Name:	79, General and Plastic Surgery Panel GEX, Laser powered surgical instrument

III. Predicate Devices

- Iris Medical Oculight SL/SLx (K020374, K913430, K912918)
- Nidek DC-3300 (K013760)
- Nidek DC-3000 (K903639)
- BV International Viridis Laser (K960867)
- Coherent System 920 Argon/Krypton (K830235)
- Novus Varia Ophthalmic Laser (K022181)
- LaserLink Z, LaserLink Z-1000 (K022181)
- LaserLink HS (K973470)
- Iridex Large Spot Slit Lamp Delivery Adapters (K020374)
- Nidek Slit Lamp Delivery Adapter for Nidek SL-1600 (K013760)
- Lumenis Laser Indirect Ophthalmoscope (K022181)
- Iris Laser Indirect Ophthalmoscope (K020374)
- Acculite Endophotocoagulation Probe Delivery System (Acculite Endoprobe/Endokit) (K022181);
- HGM EndoOcular Probe (K840590, K860358)
- Iris Medical Endoprobe (K020374, K96097)

IV. Product Description

The Novus TTx Laser is an air cooled, solid-state, diode laser system intended for use in the treatment of ocular pathology as stated in Section V. The Novus TTx is a semiconductor diode laser that operates at a single wavelength, 810nm, with treatment beam power output ranging from 0 to 2 Watts. 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; a covered footswitch; operating software; an optional remote control unit; and delivery devices with accessories. Compatible delivery devices include: the LaserLink Z and LaserLink Z-1000 Slit Lamp Delivery Adapters, the LaserLink HS Slit Lamp Delivery Adapter, the LaserLink Large Spot Slit Lamp Delivery Adapters (LaserLink HS, LaserLink Z and Universal LaserLink), the Laser Indirect Ophthalmoscope, and the Acculite Endophotocoagulation Probe Delivery System (Acculite EndoOcular Probe/Endokit).

V. Indications for Use

The Novus TTx Laser and Delivery Devices is intended for use in the treatment of ocular pathology. The Novus TTx 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:
  - Diabetic retinopathy (proliferative retinopathy, nonproliferative retinopathy, macular edema);
  - Retinal tears, detachments and holes
  - Lattice degeneration
  - Age-related macular degeneration
  - Intraocular tumors (choroidal hemangioma, choroidal melanoma, retinoblastoma)
  - Retinopathy of prematurity
  - Choroidal neovascularization;
  - Central and branch retinal vein occlusion;

- 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 TTx Laser and Delivery Devices with Accessories have the same intended uses and indications for use as the predicate devices, and have similar technological characteristics as the predicate devices - treatment wavelength, laser media, mode of operation, power output, exposure duration, treatment intervals, spot sizes, aiming beam, cooling system, laser energy delivery control (footswitch), and delivery systems - as the predicate devices, and therefore is substantially equivalent to the predicate devices referenced in Section III

VII. Performance Data

System and software hazard analysis information, software verification and validation information, and clinical literature were 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 TTx Laser and Delivery Devices and the predicate laser systems and the evaluation of the performance data.

VIII. Conclusion

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2003

Ms. Karen L. Baker
Senior Manager, Regulatory Affairs
Lumenis, Inc.
2400 Condensa Street
Santa Clara, California 95051-0901

Re: K032357
Trade/Device Name: Novus TTx Laser and Delivery Devices with Accessories
Regulation Number: 21 CFR 878.4810, 886.4390
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in Dermatology; Ophthalmic laser
Regulatory Class: II
Product Code: GEX, HQF
Dated: July 28, 2003
Received: July 31, 2003

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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for 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): K032357

Device Name: **Novus TTx Laser and Delivery Devices with Accessories**

Indications for Use:

The Novus TTx Laser and Delivery Devices is intended for use in the treatment of ocular pathology. The Novus TTx 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:
  - Diabetic retinopathy (proliferative retinopathy, nonproliferative retinopathy, macular edema);
  - Retinal tears, detachments and holes
  - Lattice degeneration
  - Age-related macular degeneration
  - Intraocular tumors (choroidal hemangioma, choroidal melanoma, retinoblastoma)
  - retinopathy of prematurity
  - choroidal neovascularization;
  - central and branch retinal vein occlusion;

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)
Optional Format 1-2-96

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032357

Attachment 2, Continued
Indications for Use Statement as Requested by FDA

510(K) Number (if Known): K032357

Device Name: **Novus TTx Laser and Delivery Devices with Accessories**

Indications for Use:

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)
Optional Format 1-2-96

Miriam C Provost
(Division Sign-Off)
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