

K052526

NOV 15 2005

510 (k) Summary

General Information:

Submitter: Lumenis, Inc.
2400 Condensa Street
Santa Clara, CA 95051

Contact Person: Karen Baker
Tel: (408) 764-3603
Fax: (408) 764-3934

Summary Date of Preparation: September 12, 2005

Names:

Proprietary Name: Novus® 3000 Laser System and Delivery Devices
Common Name: Nd:YAG Laser
Classification Name: Laser Instrument, Surgical, Powered (21 CFR 878.4810, Product Code 79 GEX)

Predicate Devices:

Novus® Varia (K022181)
Novus® Spectra (K022327)
LaserLink Zeiss Slit Lamp Delivery Adapters (LaserLink Z and Z-1000) (K022181, K022327, K032357)
LaserLink HS Slit Lamp Laser Delivery Adapter (K022327, K032357)
Lumenis 1000 Integrated Slit Lamp (K052129)
Laser Indirect Ophthalmoscope (Heine and Keeler models) (K022181, K022327, K032357)
Lumenis Acculite Endophotocoagulation Probe
Delivery System (Acculite Endoprobe/Endokit) (K022181, K022327, K032357)
Illuminating EndoOcular Probe (K022357, K931784)
Aspirating EndoOcular Probe (K022357, K931072)

Lumenis's Novus® 3000 Laser System and Delivery Devices is substantially equivalent to the Lumenis Novus® Varia and the Lumenis Novus® Spectra manufactured and distributed by Lumenis, Inc. Salt Lake City, Utah. The Novus® 3000 Ophthalmic Laser System with Delivery Devices and Accessories share the same intended uses, 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 (foot switch), and delivery systems as the predicate devices identified above.

Device Description

Lumenis, Inc.'s Novus® 3000 Laser System with the Delivery Devices is an air cooled, diode-pumped, solid state, Nd:YAG Laser System, which produces a wavelength of 532 nm of laser light with a treatment beam output ranging from 50 mw to 3.0 W. The main parts of the Novus® 3000 system include the laser console, a footswitch, a remote control and assorted laser accessories.

K052/20

Intended Use:

The Novus 3000 Laser System is intended for use in the treatment of ocular pathology. The Novus 3000 Laser System 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, 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 the delivery of laser energy in eyes with retinal pathology. The Laser Indirect Ophthalmoscope is indicated for use in the following ophthalmic treatments and conditions: diabetic retinopathy (panretinal photocoagulation); peripheral neovascularization, retinal breaks, detachments, and tears, lattice degeneration, pneumatic retinopexy reattachment procedures, segmental peripheral photocoagulation; segmental photocoagulation; cloudy vitreous cavities; pediatric retinal repairs (under general anesthesia), delivery of laser energy through small pupils or to eyes with focal lens opacities.

Endophotocoagulation

The Acculite EndoOcular Probe 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.

The laser delivery function of the Acculite Acculite EndoOcular Probes (Acculite EndoOcular Probe, Acculite Aspirating EndoOcular Probe and Acculite Illuminating EndoOcular Probe) is indicated for use in ocular surgery to deliver laser energy to the treatment area selected by the surgeon.

The aspiration function of the Acculite Aspirating EndoOcular Probe is indicated for use when unwanted fluid is present in the eye during ocular surgery, causing refraction or scattering of the laser beam from the intended treatment site.

The illumination function of the Acculite Illuminating EndoOcular Probe is indicated for use during ocular surgery to illuminate the interior of the eye.

1052526

Technological Characteristic Similarities

The Novus 3000 Laser System and Delivery Devices is similar in intended use and mode of operation to the Lumenis Novus® Varia and the Lumenis Novus® Spectra. The Novus 3000 Laser System and Delivery Devices, the Novus Varia and the Novus Spectra all utilize a frequency doubled ND:YAG, diode-pumped solid state system. The laser control system, mode of operation, laser actuation, pulse counter, treatment intervals, aiming beam and the exposure times, which are adjustable in variable increments, are the same for the predicate devices as well as the Novus 3000® Laser System. In addition, the same Delivery Systems are available for the predicate devices and the Novus 3000.

Performance Data:

No performance data is required for this Class II device nor requested by the Food and Drug Administration (Office of Device Evaluation). No data was submitted for section 807.92 6[(b)(1)(2)(3c)].

Conclusion:

The Novus® 3000™ with Delivery Devices is substantially equivalent to the Novus Varia Ophthalmic Laser and Delivery Devices and the Novus Spectra Laser with Delivery Devices. The Novus® 3000™ Laser with Delivery Devices share the same intended use, indications for use, and technological characteristics as the predicate ophthalmic laser systems.



NOV 15 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Karen Baker
Manager, Regulatory Affairs
Lumenis, Inc.
2400 Condensa Street
Santa Clara, California 95051

Re: K052526

Trade/Device Name: Novus 3000 Laser and Delivery Devices

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic
surgery and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: September 12, 2005

Received: September 14, 2005

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 (240) 276-0115. 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/industry/support/index.html>.

Sincerely yours,

A handwritten signature in cursive script that reads "Barbara Buchman" with a small "for" written below it.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052526

Device Name: Novus 3000 Laser and Delivery Devices

Indications For Use:

The Novus 3000 Laser System is intended for use in the treatment of ocular pathology. The Novus 3000 Laser System 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, 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 the delivery of laser energy in eyes with retinal pathology. The Laser Indirect Ophthalmoscope is indicated for use in the following ophthalmic treatments and conditions: diabetic retinopathy (panretinal photocoagulation); peripheral neovascularization, retinal breaks, detachments, and tears, lattice degeneration, pneumatic retinopexy reattachment procedures, segmental peripheral photocoagulation; segmental photocoagulation; cloudy vitreous cavities; pediatric retinal repairs (under general anesthesia), delivery of laser energy through small pupils or to eyes with focal lens opacities.

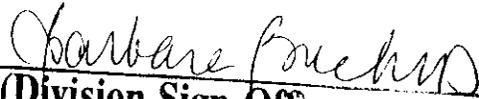
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(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**

510(k) Number K052526

Indications for Use

510(k) Number (if known):

Device Name: K052526 Novus 3000 Laser and Delivery Devices

Indications For Use, Continued:

Endophotocoagulation

When used with a Novus 3000 Laser System, the Acculite EndoOcular Probes (Acculite EndoOcular Probe, Acculite Aspirating EndoOcular Probe, and Acculite Illuminating EndoOcular Probe) are intended 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.

The laser delivery function of the Acculite EndoOcular Probes (Acculite EndoOcular Probe, Acculite Aspirating EndoOcular Probe and Acculite Illuminating EndoOcular Probe) is indicated for use in ocular surgery to deliver laser energy to the treatment area selected by the surgeon.

The aspiration function of the Acculite Aspirating EndoOcular Probe is indicated for use when unwanted fluid is present in the eye during ocular surgery, causing refraction or scattering of the laser beam from the intended treatment site.

The illumination function of the Acculite Illuminating EndoOcular Probe is indicated for use during ocular surgery to illuminate the interior of the eye.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K052526