AUG 3 0 2005

Attachment 8
510(k) Summary Statement

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:	August 24, 2005

II. Names

Device Names:	Lumenis 1000 Integrated Slit Lamp
Primary Classification Name:	79, General and Plastic Surgery Panel GEX, Laser powered surgical instrument

III. Predicate Devices

Lumenis (Coherent) LaserLink Z-1000 Slit Lamp Laser Delivery Adapter [K022181, K022327, K000498]
Lumenis (HGM) M140 Integrated Slit Lamp (K990174, K022327, K981952)

IV. Product Description

The Lumenis 1000 Integrated Slit Lamp consists of an ophthalmic laser delivery system and an associated eye safety filter that has been integrated into a conventional slit lamp to provide the most efficient means to diagnose and treat ocular disease. The Lumenis 1000 Integrated Slit Lamp consists of: (1) a slit lamp with parallel binocular optics and five-position magnification, (2) SureSpot™ 1000 µm laser delivery telescope, (3) laser aiming and treatment beam micromanipulator (4) an internal three-color ClearView™ laser eye safety filter, and (5) an electrically adjustable table with slit lamp power supply, elbow rest, laser mounting tray, and laser power outlets.

V. Indications for Use

The Lumenis 1000 Integrated Slit Lamp laser delivery system is indicated for a variety of ophthalmic diagnostic and treatment uses including, but not limited to, the indications specified in the compatible laser's Operator Manuals. The Lumenis 1000 Integrated Slit Lamp may be used in the medical specialties or procedures that have been given market clearance by the Food and Drug Administration through the compatible laser systems. The Lumenis 1000 Integrated Slit Lamp is compatible with Lumenis lasers only.

VI. Rationale for Substantial Equivalence

The Lumenis 1000 Integrated Slit Lamp shares the same indications for use, similar design features, and functional features and is therefore substantially equivalent to the legally marketed predicate devices.

VII. Safety and Effectiveness Information

The specifications and intended uses of the Lumenis 1000 Integrated Slit Lamp is the same or similar to that for the claimed predicate devices. There have been no significant changes or modifications from the predicate devices that affect the safety or effectiveness of the Lumenis 1000 Integrated Slit Lamp.

The determination of substantial equivalence was based upon the comparison of the technical characteristics between the Lumenis 1000 Integrated Slit Lamp and the predicate laser systems.

VIII. Conclusion

The Lumenis 1000 Integrated Slit Lamp is substantially equivalent to similar predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2005

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

Re: K052129
Trade/Device Name: Lumenis 1000 Integrated Slit Lamp
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: August 3, 2005
Received: August 5, 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/dsma/dsmamain.html

Sincerely yours,

Barbara Buehrmp
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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): K052129

Device Name: Lumenis 1000 Integrated Slit Lamp

Indications For Use: The Lumenis 1000 Integrated Slit Lamp laser delivery system is indicated for a variety of ophthalmic diagnostic and treatment uses including, but not limited to, the indications specified in the compatible laser's Operator Manuals. The Lumenis 1000 Integrated Slit Lamp may be used in the medical specialties or procedures that have been given market clearance by the Food and Drug Administration through the compatible laser systems. The Lumenis 1000 Integrated Slit Lamp is compatible with Lumenis lasers only.

Prescription Use ___X___ 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 CDRH, Office of Device Evaluation (ODE)

Barbara Buell MD

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

510(k) Number K052129