K081704

SEP 11 2008

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. SUBMITTER INFORMATION:

Submitter's Name:	Lumenis, Inc.
Address:	3959 W. 1820 S. Salt Lake City, UT 84104
Contact:	Tina Mayer, RAC
Phone:	(801) 656-2543
Fax:	(801) 656-2321
Date of Preparation:	June 13, 2008

B. DEVICE NAME:

Trade Name(s):	Selecta Family of Ophthalmic Laser Systems
Common/Usual Name:	Ophthalmic Laser, Surgical Laser
Classification Names:	79 GEX, Laser Powered Surgical Instrument 86 HQF, Laser, Ophthalmic
CFR Reference:	21 CFR 878.4810, Laser surgical instrument for use in general and plastic surgery and in dermatology 21 CFR 886.4390, Ophthalmic laser

C. PREDICATE DEVICE NAMES:

Trade Name(s):
1) Lumenis Selecta Duet (K021550)
2) Coherent Popeye Ophthalmic Laser System (EPIC I and EPIC IV), (K97340)
3) LaserLink Z-1000 (Z022181)

D. DEVICE DESCRIPTION:

The Lumenis Selecta is a fully integrated, high-performance diagnostic slit lamp and therapeutic laser delivery system. Selecta has all of the standard controls and functions of a diagnostic slit lamp and is intended for use in eye examination of the anterior segment, from the cornea epithelium to the posterior capsule.

The Lumenis Selecta is also an ophthalmic surgical laser designed for performing photodisruption of ocular tissue using laser energy emitted by a Nd:YAG laser including discission of the posterior capsule of the eye (posterior capsulotomy), discission of pupillary membranes (pupillary membranectomy), and iridotomy/iridectomy; and selective laser trabeculoplasty.

The Selecta Family of Ophthalmic Lasers is comprised of:

Selecta 1064: A Nd:YAG laser providing Q-switched laser pulses at a

wavelength of 1064 nm for use in photodisruption of ocular tissue (posterior capsulotomy, papillary membranectomy, and iridotomy).

Selecta SLT: A Nd:YAG laser providing Q-switched laser pulses at a wavelength of 532 nm for use in selective laser trabeculoplasty.

Selecta Duet: A Nd:YAG laser providing Q-switched laser pulses at a wavelength of 1064 nm for use in photodisruption or Q-switched frequency doubled laser pulses at a wavelength of 532 nm for use in selective laser trabeculoplasty, depending on the mode selected.

LaserLink S: Laser delivery adapter that may be coupled to each of the above Selecta models and connected to a currently cleared Lumenis 532 nm retinal photocoagulator (Novus Spectra, Novus Varia) to allow use of the slit lamp to deliver 532 nm continuous wave laser energy for retinal photocoagulation.

Selecta Duo: A Nd:YAG laser providing Q-switched laser pulses at a wavelength of 1064 nm for use in photodisruption or Q-switched 532 nm continuous wave laser energy for retinal photocoagulation.

Selecta Trio: A Nd:YAG laser providing Q-switched laser pulses at a wavelength of 1064 nm for use in photodisruption, Q-switched frequency doubled laser pulses at a wavelength of 532 nm for use in selective laser trabeculoplasty, or Q-switched 532 nm continuous wave laser energy for retinal photocoagulation, depending on the mode selected.

The Selecta produces short, individual pulses of focused laser light with wavelengths of either 1064 nm or 532 nm, depending on the selected operational mode. Using a slit lamp microscope and aiming beam, the pulsed light is accurately targeted on a structure within the patient's eye.

When the photodisruptor mode is selected, the treatment wavelength is 1064 nm. A twin-aiming beam targets the area of tissue disruption. The energy contained within a single short pulse is concentrated by focusing to a very small spot size so that plasma formation occurs at the focal point. This creates an acoustic wave which disrupts nearby tissue.

When the SLT mode is selected, the treatment wavelength is 532 nm. A coaxial aiming beam targets the trabecular meshwork via a contact lens. The SLT treatment laser provides a low energy, short pulse of laser light that produces a thermal effect in pigmented cells in the trabecular meshwork.

If the optional LaserLink S adapter is attached to the Selecta system and the compatible Lumenis Spectra 532 nm retinal photocoagulator laser, the Selecta works strictly as a diagnostic slit lamp – all photodisruptor and SLT laser functions are disabled. The LaserLink S laser delivery adaptor is used for treatments specifically cleared for the compatible laser retinal photocoagulator.

The principles of operation and fundamental scientific technology are the same for the subject devices and predicate devices.

E. INTENDED USE:

The intended use for the Selecta Family of Ophthalmic Laser Systems (Selecta 1064, Selecta SLT, Selecta Duet, LaserLink S, Selecta Duo, and Selecta Trio) and Accessories are as follows:

Selecta 1064: Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy/iridectomy.

Selecta SLT: Selective laser trabeculoplasty.

Selecta Duet: Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy/iridectomy and selective laser trabeculoplasty.

LaserLink S: Laser delivery system for use by an ophthalmologist in the treatment of ocular tissue. The laser delivery system is intended for a variety of ophthalmic uses, including the indications specified in the laser operator manual. Refer to the laser operator manual, General Intended Use section.

Selecta Duo: Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy/iridectomy and retinal photocoagulation.

Selecta Trio: Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy/iridectomy, retinal photocoagulation and selective laser trabeculoplasty.

The intended use has not changed from the predicate devices (K021550, K97340, K022181).

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY & SUBSTANTIAL EQUIVALENCE

The subject device, the Selecta Family of Laser Systems, has the same intended use, general design and fundamental scientific technology as the predicate devices (K021550, K97340, K022181).

The Selecta Family of Laser Systems uses technology substantially equivalent to the Lumenis Selecta Duet (K021550), Coherent Popeye Ophthalmic Laser System (EPIC I and EPIC IV), (K97340), and the LaserLink Z-1000 (Z022181). There are no new hazards introduced by the Selecta Family of Laser Systems as compared with the predicate devices.

G. PERFORMANCE DATA SUMMARY:

The appropriate testing including safety, performance and functional testing to determine substantial equivalence of the Selecta Family of Laser Systems has been conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2008

Lumenis, Inc.
% Ms. Tina Mayer
Regulatory Affairs Specialist
3959 West 1820 South
Salt Lake City, Utah 84104

Re: K081704
Trade/Device Name: Selecta Family of Laser Systems
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser.
Regulatory Class: II
Product Code: GEX, HQF
Dated: June 13, 2008
Received: June 17, 2008

Dear Ms. Mayer:

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.

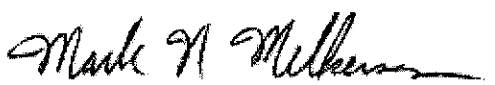
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

1.3 Indications for Use Statement

510(k) Number (if known): K081704

Device Name: Selecta Family of Laser Systems

Indications for Use:

The Indications for use for the Selecta Family of Ophthalmic Laser Systems (Selecta 1064, Selecta SLT, Selecta Duet, LaserLink S, Selecta Duo, and Selecta Trio) and Accessories are as follows:

Selecta 1064: Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discussion of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy/iridectomy.

Selecta SLT: Selective laser trabeculoplasty.

Selecta Duet: Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy/iridectomy and selective laser trabeculoplasty.

LaserLink S: Laser delivery system for use by an ophthalmologist in the treatment of ocular tissue. The laser delivery system is intended for a variety of ophthalmic uses, including the indications specified in the laser operator manual. Refer to the laser operator manual, General Intended Use section.

Selecta Duo: Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy/iridectomy and retinal photocoagulation.

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Selecta Trio: Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy/iridectomy, retinal photocoagulation and selective laser trabeculoplasty.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____

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

510(k) Number K081704