K 051944

SEP 30 2005

Attachment 10
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:	July 15, 2005

II. Names

Device Names:	Family of Selecta Ophthalmic Laser Systems, Delivery Device and Accessories Selecta 1064 Ophthalmic Laser System Selecta SLT Ophthalmic Laser System Selecta Duo Ophthalmic Laser System LaserLink S
Primary Classification Name:	79, General and Plastic Surgery Panel GEX, Laser powered surgical instrument

III. Predicate Devices

- Lumenis Selecta Duet (K021550)
- Coherent Popeye Ophthalmic Laser and Coherent Popeye Ophthalmic Laser in Combination with the Coherent Ultima 2000 Laser Photocoagulator Coherent Popeye Nd:YAG Ophthalmic Laser Systems (K973470)
- Selecta 7000 Frequency Doubled Q-Switched Nd:YAG Ophthalmic Laser (K004006)
- LaserLink Z-1000 (K022181)

IV. Product Description

The Lumenis Selecta is a fully integrated flash lamp pumped, solid state, Nd:YAG ophthalmic surgical laser system intended for use in the treatment of ocular pathology and for use as a diagnostic slit lamp.

The Family of Selecta Ophthalmic Lasers, Delivery Device and Accessories consists of the following models:

1) **Selecta 1064®** — a Nd:YAG laser providing Q-switched laser pulses at a wavelength of 1064nm for use in photodisruption of ocular tissue (posterior capsulotomy, pupillary membranectomy, iridotomy). The 1064nm treatment beam delivers a 4 nsec, 0.3-10mJ adjustable and selectable single, double or triple pulse of energy. It is

conditioned through beam shaping optics to generate a photodisruption micro pulse of plasma at a precision adjustable location relative to the visual focal plane (located at slit lamp center of rotation) and along the slit lamp objective lens axis. A twin aiming beam is also focused by the slit lamp objective to a converging 20μm spot located at the focal point of the lens. The focal point of photodisruption is adjustable 0-350μm in the posterior direction by the physician relative to this convergence of the twin aiming beams.

2) **Selecta SLT®** — a Nd:YAG laser providing Q-switched frequency doubled pulses at a wavelength of 532nm for use in selective laser trabeculoplasty. The treatment beam delivers a 4nsec, 0.1-2mJ adjustable single pulse of energy. The aiming and treatment beams are coaxial with each other and focused by the slit lamp objective to a 400μm spot at the focal point of the lens.

3) **Selecta Duo®** — a Nd:YAG laser providing Q-switched laser pulses at a wavelength of 1064 nanometers for use in photodisruption or Q-switched frequency doubled pulses at a wavelength of 532nm for use in selective laser trabeculoplasty, depending upon the mode selected. The Selecta Duo contains two aiming beam modules that produce a single beam for the 532nm mode and a dual beam for the 1064nm mode, respectively.

For each Selecta model, the physician controls delivery of laser energy from the Selecta remote control display unit and activates the treatment laser beam with a footswitch or joystick pushbutton. In addition, a laser slit lamp delivery adaptor, the **LaserLink S**, may be coupled to each of the above Selecta models and connected to a currently cleared Lumenis 532nm photocoagulator to allow the physician to use the Selecta slit lamp to deliver 532nm continuous wave laser energy for photocoagulation.

V. Indications for Use

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

Selecta SLT: selective laser trabeculoplasty

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; and

selective laser trabeculoplasty

The Selecta 1064, Selecta SLT and Selecta Duo Ophthalmic Lasers are also intended for use as a diagnostic slit lamp, specifically,

An AC-powered slit lamp biomicroscope intended for use in eye examination of the anterior segment, from the cornea epithelium to the posterior capsule. It is used to aid in

the diagnosis of diseases or trauma which affects the structural properties of the anterior segment

LaserLink S: laser delivery system for use by an ophthalmologist in the treatment of ocular tissue;

laser delivery system indicated for use for a variety of ophthalmic uses, including the indications specified in the laser operator manual. Refer to the laser operator manual, Indications for Use section.

VI. Rationale for Substantial Equivalence

The Family of Selecta Ophthalmic Laser Systems, Delivery Device and 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, energy output, pulse duration, pulse settings, spot sizes, aiming beam, cooling system, laser energy delivery control (footswitch/ handswitch), and delivery system - as the predicate devices, and therefore are 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 Family of Selecta Ophthalmic Laser Systems, Delivery Device and Accessories and the predicate laser systems and the evaluation of the performance data.

VIII. Conclusion

The Family of Selecta Ophthalmic Laser Systems, Delivery Device and Accessories are substantially equivalent to similar predicate laser devices, delivery systems and accessories. The Family of Selecta Ophthalmic Laser Systems, Delivery Device and Accessories 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

SEP 30 2005

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

Re: K051944
Trade/Device Name: Family of Selecta Ophthalmic Laser Systems (Selecta SLT, Selecta 1064, and Selecta Duo) and Delivery Device (LaserLink S) and Accessories
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: II
Product Code: HQF, GEX
Dated: July 15, 2005
Received: July 18, 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,

Mark N. Melkerson
Acting 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): K 051944

Device Name: **Family of Selecta Ophthalmic Laser Systems (Selecta SLT, Selecta 1064, and Selecta Duo) and Delivery Device (LaserLink S) and Accessories**

Indications for Use:

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 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

selective laser trabeculoplasty

The Selecta 1064, Selecta SLT and Selecta Duo Ophthalmic Lasers are also intended for use as a diagnostic slit lamp, specifically,

An AC-powered slit lamp biomicroscope intended for use in eye examination of the anterior segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affects the structural properties of the anterior segment.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K051944

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

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

510(K) Number (if Known): K051944

Device Name: **Family of Selecta Ophthalmic Laser Systems (Selecta SLT, Selecta 1064, and Selecta Duo) and Delivery Device (LaserLink S) and Accessories**

Indications for Use:

LaserLink S: laser delivery system for use by an ophthalmologist in the treatment of ocular tissue;

laser delivery system indicated for use for a variety of ophthalmic uses, including the indications specified in the laser operator manual. Refer to the laser operator manual, Indications for Use section.

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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

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

510(k) Number K051944