K081774

SEP 1 2 2008

Revised August 11, 2008

510(k) Summary of safety and effectiveness

APPLICANT	SOLX, Inc.
TRADE NAME:	SOLX 790 Titanium Sapphire Laser
COMMON NAME:	Ophthalmic Laser
CLASSIFICATION NAME:	Ophthalmic lasers for use in laser trabeculoplasty
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE	CFR 886.4390 Product code HQF (laser, ophthalmic) and CFR 878.4810 Product code GEX (laser surgical instrument).
PREDICATE DEVICE:	***ULTIMA 2000 ARGON LASER K913127***
USER FEE PAYMENT ID:	

SUBSTANTIALLY EQUIVALENT TO:

COHERENT (LUMENIS)	Ultima 2000 Argon Laser	K913127

The SOLX 790 Titanium Sapphire Laser is substantially equivalent in intended of action to the Coherent/Lumenis Ultima 2000 Argon Laser approved under K913127.

5.1 DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The SOLX 790 Titanium Sapphire system is a flashlamp-pumped laser intended for use in performing laser trabeculoplasty. The laser operates at a wavelength of 790 nanometers (nm), and delivers user-selectable pulse energies of 30-80 millijoules (mJ), with nominal pulse duration of 8 microseconds (7±2μsec) and a nominal spot size of 200 microns (μm). A footswitch activates the laser to deliver pulses of laser energy through an optical fiber to a slit lamp. A trained physician then directs the laser pulses exiting the slit lamp to the desired regions of the trabecular meshwork inside the eye using a Goldman goniolens. A low power, visible aiming beam allows the physician to direct the treatment laser pulses.

PRODUCT INFORMATION

The laser is comprised of the following functional components:

- Electronics Module
- Laser Optical Head
- Control Panel
- Slit Lamp/Slit Lamp Table
- Covered Footswitch

Table A
Comparison of SOLX 790 Titanium Sapphire Laser and Predicate Device

	SOLX 790 Titanium Sapphire Ophthalmic Laser	Coherent Ultima 2000 Argon Ophthalmic Laser K913127
Indications for Use	Laser trabeculoplasty to reduce intraocular pressure in patients with poorly controlled intraocular pressure on maximally tolerated medical therapy or prior failed laser trabeculoplasty	[a] Indicated for use in the treatment of ocular pathology including trabeculoplasty in open-angle glaucoma
Clinical Treatment Power/Energy	30-80mJ	50-1750 mW
Pulse duration	7±2 microseconds	0.01–1.0 sec
Laser Media	Titanium Sapphire	Argon
Wavelength	790 nm ± 5 nm	[b]488/514 nm (blue-green)
Mode of Operation	pulsed	CW
Spot Size	200 um	[c]50-1000 μm
Aiming Beam	Diode, variable intensity to < 5 mW	Diode, variable intensity from barely visible to 1.5 mW
Laser Actuation	Footswitch	Footswitch
Slit Lamp/Slit Lamp Adapters	Laser compatible slit lamp	Laser compatible slit lamps
Cooling System	Internal water cooled	Air cooled
Dimensions	Height: 38" (96 cm) Width: 16" (40 cm) Depth: 27" (68 cm), including cord wrap	47 cm x 20 cm x 60 cm (18.5" x 8" x 24") (h x w x d)
Weight	Weight: 140 lbs (81 kg)	30 kg (65 lbs)
Electrical Requirements	120 VAC/ 15 Amps – It can also be run from 200-240 VAC service. The system draws approximately 500 Watts. 50-60 Hz	100-120 VAC; 15-20 A 220-240 VAC; 10 A 50/60 Hz

5.2 INDICATION FOR USE: SOLX 790 TITANIUM

Laser trabeculoplasty to reduce intraocular pressure in patients with poorly controlled intraocular pressure on maximally tolerated medical therapy or prior failed laser trabeculoplasty.

5.3 RATIONALE FOR SUBSTANTIAL EQUIVALENCE

The Titanium Sapphire Laser shares the same indications for use and similar design features (treatment area, aiming beam, delivery system, similar cooling system, and control system) as the predicate device. The Titanium Sapphire Laser has different functional features from the predicate device, including energy delivered and spot size. The effects of the new functional

features in performing trabeculoplasty have been assessed through preclinical and clinical investigations. The data obtained from these investigations demonstrate that the Titanium Sapphire Laser is substantially equivalent to the predicate laser system.

5.4 Safety and Effectiveness Information

Preclinical and clinical data was provided to demonstrate that the Titanium Sapphire is safe and effective for use in trabeculoplasty to reduce intraocular pressure in patients with poorly controlled or elevated intraocular pressure or prior failed laser trabeculoplasty.

In addition, hazard analysis information was provided.

5.5 Conclusion

The Titanium Sapphire Laser is substantially equivalent to currently marketed predicate laser device. The device shares the same intended use/indications for use and other basic system characteristics as the predicate laser system. Preclinical and clinical study results demonstrate the substantial equivalence as well as the safety and effectiveness of the Titanium Sapphire Laser for use in trabeculoplasty.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2008

SOLX, Inc.
c/o Mr. Doug Adams
President SOLX, Inc.
890 Winter Street, Suite 115
Waltham, MA 02451

Re: K081774
Trade/Device Name: SOLX 790 Titanium Sapphire Laser
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF, GEX
Dated: June 19, 2008
Received: June 26, 2008

Dear Mr. Adams:

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,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ~~TBD~~ K081774

Device Name: SOLX 790 Titanium Sapphire Laser

Laser trabeculoplasty to reduce intraocular pressure in patients with poorly controlled intraocular pressure on maximally tolerated medical therapy or prior failed laser trabeculoplasty

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

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