

AUG 14 2009

510(K) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a).

SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON, AND DATE SUMMARY PREPARED

- a. Applicant: LenSx Lasers, Inc.
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Aliso Viejo, CA 92656
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- b. Contact Person: Judy Gordon, D.V.M.
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NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME

- a. Trade/Proprietary Name: LenSx 550 Laser System

- b. Common/Usual Name: LenSx 550 Laser System

- c. Device Classification: Ophthalmic Femtosecond Laser, Class II,
21 CFR 886.4390

- d. Product Code: OOE

PREDICATE DEVICES

510(k) #	TRADE NAME	MANUFACTURER
K001498	The Fugo Blade	Medisurg Research and Management Corp.
K040005	Profile 3000 laser System and Delivery Devices and Accessories	Sciton, Inc.
K052806	Burane Laser System	WaveLight Laser Technologie, AG
K021548	Fotona Dualis Nd:YAG/Er:YAG Laser System	Fontona D.D.
K033354	FEMTEC Laser Microkeratome	20/10 Perfect Vision Optische Gerate GMBH
K993153, K001211, K002890, K013941, K031960, K041893, K060372, K063682, and K073404	IntraLase FS Lasers	IntraLase Corp.

DEVICE DESCRIPTION

The LenSx 550 Laser is an ophthalmic surgical laser intended for use in patients requiring an anterior capsulotomy. The LenSx 550 Laser focuses a beam of low energy pulses of infrared light into the anterior lens. Consistent with commercially available femtosecond lasers used for lamellar resection of the cornea (GEX, 878.4810), the cutting effect is produced by scanning individual pulses to produce a continuous incision. The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired location. A computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision. Finally, the laser pulses are delivered through an off-the-shelf disposable contact lens that contacts the cornea and fixes the eye with respect to the delivery system.

STATEMENT OF INTENDED USE

The LenSx 550 Laser System is indicated for anterior capsulotomy during cataract surgery.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The LenSx 550 laser shares a similar intended use, and indication for use as the Fugo Blade by Medisurg Research and Management Corp., the Profile 3000 Laser System (K040005), the Burane Laser System (K052806) and the Fontona Dualis Nd:YAG/Er:YAG Laser System (K021548). The LenSx 550 mode of operation and the technology utilized to create the cutting action are similar to the 20/10 Perfect Vision FemTec Laser Microkeratome, and the IntraLase FS Lasers and is therefore substantially equivalent to these legally marketed predicate devices.

BRIEF SUMMARY OF NONCLINICAL TESTS AND RESULTS

LenSx has developed the LenSx 550 for use in anterior capsulotomy, employing the precision and control of femtosecond lasers for this procedure. Pre-clinical and clinical testing has included bench testing and a prospective, single-center clinical trial.

Summary of Pre-Clinical Testing

Testing and analyses performed included accuracy and reproducibility of capsulotomy size and depth in porcine eyes and plastic substrates, as well as scanning electron microscopy. The data demonstrated the LenSx 550 produces anterior capsulotomies that are uniform, accurate and predictable in size over a wide range of depths. The capsular edge created by the LenSx 550 is also at least as smooth as that created during manual anterior capsulotomy.

Summary of Clinical Testing

A clinical trial of the LenSx 550 Laser was conducted to evaluate the performance of this laser system in the creation of anterior capsulotomy during cataract/IOL surgery. Anterior capsulotomy was successfully performed in all eyes using the LenSx 550 Laser, i.e., the capsulotomy was complete in all eyes, with no radial tears observed intraoperatively or postoperatively, and with an intraocular lens placed in the capsular bag. Postoperatively, the course of follow-up in the study population was unremarkable. The intraocular lens was centered in all study eyes, and no posterior capsule tears were observed. All capsulotomies were judged to be well centered by the surgeon using visual inspection in the operating microscope.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

LenSx Lasers, Inc.
c/o Judy Gordon, D.V.M.
Regulatory Consultant to LenSx Lasers, Inc.
ClingReg Consulting Services, Inc.
733 Bolsana Drive
Laguna Beach, CA 92651

AUG 14 2009

Re: K082947
Trade/Device Name: LenSx 550 Laser System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: II
Product Code: OOE
Dated: July 8, 2009
Received: July 9, 2009

Dear Dr. Gordon:

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.

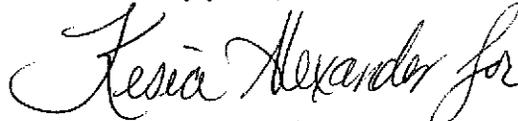
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in cursive script that reads "Malvina B. Eydelman for".

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K082947

Device Name(s): LenSx 550 Laser System

Indications for Use:

The LenSx 550 Laser System is indicated for anterior capsulotomy during cataract surgery.

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)

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Bruce Drum
(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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