DEC 11 2009

2.0 510(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).

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

a.	Applicant:	LenSx Lasers, Inc. 33 Journey, Suite 175 Aliso Viejo, CA 92656 Tel: (949) 360-6010 Fax: (949) 360-6028
b.	Contact Person:	Judy Gordon, D.V.M. ClinReg Consulting Services, Inc. 733 Bolsana Drive Laguna Beach, CA 92651 judy@clinregconsulting.com Tel: (949) 715-0609 Fax: (949) 715-0610

2.2 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.	Classification Name:	Laser Instrument, Surgical, Powered
d.	Classification Code(s):	21 CFR 886.4390 ; 79 OOE

2.3 PREDICATE DEVICES

510(K) #	TRADE NAME	MANUFACTURER
K082947	LenSx 550 Laser System	LenSx Lasers, Inc.
K041893	IntraLase FS Laser	Abbott Medical Optics
K981063	Automated Corneal Trephine	Laser Center Development Corporation
K013151	ASMOTOM Automated Trephine System	BKG Ophthalmics USA, Inc
K864520	Barron Rotary Blade Trephine Using Hessburg-Barron	Precision Instruments, Inc.
K861825	Corneal Transplant Trephine Disposable Blade	Storz Instrument Co.

2.4 DEVICE DESCRIPTION

The LenSx 550 Laser is an ophthalmic surgical laser indicated for use in the creation of a penetrating cut/incision for penetrating and lamellar keratoplasty. Consistent with commercially available femtosecond lasers (Product Code GEX, 878.4810 and OOE, 886.4390) the LenSx 550 Laser creates incisions using focused femtosecond laser pulses. Individual photodisruption locations are controlled by repeatedly repositioning the laser focus in the cornea. The light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is thereby photodisrupted at the laser focus. The surgical effect is produced by scanning thousands of individual pulses per second 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. The laser pulses are delivered through an off-the-shelf, disposable contact lens and suction ring assembly that contacts the cornea and fixes the eye with respect to the delivery system.

2.5 STATEMENT OF INTENDED USE

The LenSx 550 Laser System is indicated for use in the creation of a partial thickness cut/incision for lamellar keratoplasty and in the creation of a full-thickness cut/incision for penetrating keratoplasty.

The LenSx 550 laser has the same indication for use as the Automated Corneal Trephine (K981063), the ASMOTOM Automated Trephine System (K013151) and the IntraLase FS Laser (K041893).

2.6 TECHNOLOGICAL CHARACTERISTICS COMPARISON

The LenSx 550 laser has the same fundamental scientific technology and operating principle as the LenSx 550 Laser (K082947) and the IntraLase FS Laser (K041893) and is therefore substantially equivalent to these legally marketed predicate devices.

2.7 BRIEF SUMMARY OF NONCLINICAL TESTS AND RESULTS

The performance data supporting safety and substantial equivalence of the LenSx 550 femtosecond laser system to the predicate devices demonstrate the following:

- The accuracy and reproducibility of the depth and geometry of penetrating cuts/incisions
- The ability to create penetrating corneal incisions in opacified corneas
- The limited collateral tissue effects and retained endothelial cell viability adjacent to penetrating laser corneal incisions as compared to manual trephination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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

DEC 11 2009

Re: K092647
Trade/Device Name: LenSx® 550 Laser System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: II
Product Code: OOE
Dated: November 30, 2009
Received: December 1, 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" (21CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander 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): K092647

Device Name(s): LenSx 550 Laser System

Indications for Use:

The LenSx 550 Laser System is indicated for use in the creation of a partial thickness cut/incision for lamellar keratoplasty and in the creation of a full-thickness cut/incision for penetrating keratoplasty.

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)

Bruce Drum

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

510(k) Number K092647