

APR 23 2010

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.
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

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

PREDICATE DEVICES

510(k) #	TRADE NAME	MANUFACTURER
K082947	LenSx 550 Laser System	LenSx Lasers, Inc.
K993154	Dodick Laser Photolysis System	ARC Laser Corporation
K952213	Alcon Series 20000 Legacy Phacoemulsifier	Alcon Laboratories

DEVICE DESCRIPTION

The LenSx 550 Laser is an ophthalmic surgical laser that has previously been cleared for use in anterior capsulotomy during cataract surgery (K082947). The LenSx 550 generates femtosecond laser pulses that are scanned in a three-dimensional pattern in the eye. Localization of these laser pulses is accomplished by an aiming beam that identifies the surfaces of the lens, and an off-the-shelf, disposable contact lens and suction ring assembly that fixates the eye relative to the delivery system. As described in K082947, anterior capsulotomy is performed by delivering a cylindrical pattern of laser pulses to intersect the anterior lens capsule.

The same surgical device, with only minor software changes, is now also being proposed for use in phacofragmentation during cataract surgery. As described in this premarket notification, laser phacofragmentation divides the lens into quadrants, in the same way that division of the lens into quadrants is performed with standard ultrasound phacofragmentation in the initial step of phacoemulsification.

To perform phacofragmentation, the LenSx system delivers a series of laser pulses to form two intersecting ellipsoidal planes. Photodisruption of the lens tissue in this pattern, which appears as a cross from a surgical (top) view, segments the nucleus into four sections before the eye is physically entered by any instruments or devices.

Following entry into the eye and then into lens, the fragmented nuclear quadrants created by the LenSx 550 are further fragmented and removed using a standard phacoemulsification probe.

STATEMENT OF INTENDED USE

The LenSx 550 Laser System is indicated for anterior capsulotomy and laser phacofragmentation during cataract surgery. The anterior capsulotomy and phacofragmentation procedures may be performed either individually or consecutively during the same surgery.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The LenSx 550 Laser System proposed for use in phacofragmentation is identical with respect to all technological characteristics to the previously cleared LenSx 550 for use in anterior capsulotomy (K082947). Substantial equivalence is also drawn to previously cleared phacofragmentation systems.

The LenSx 550 Laser System delivers femtosecond laser pulses to produce a pattern of photodisruption in the lens nucleus. Highly localized, laser mediated acoustic and cavitation effects associated with photodisruption precisely fragment the lens nucleus.

Predicate devices include laser and ultrasound phacoemulsification devices cleared for phacofragmentation, such as the Alcon Series 20000 Legacy (Alcon Laboratories, Inc. K952213) and the Dodick Photolysis system (ARC Laser Corp., K993154). Ultrasound

phacofragmentation devices utilize a piezoelectric ultrasonic source that generates similar acoustic and cavitation effects that, along with mechanical effects from the probe, result in phacofragmentation.

Laser devices cleared for phacofragmentation, including the Dodick Photolysis System, use high energy nanosecond laser pulses delivered via a probe to create the mechanical, cavitation and acoustic effects that mediate phacofragmentation.

Since the femtosecond pulses are delivered optically through the cornea, the LenSx Laser performs phacofragmentation without the mechanical effects and ultrasonic shockwaves/energy transmitted to the tissue by handheld phacofragmentation probes.

BRIEF SUMMARY OF PRECLINICAL AND CLINICAL PERFORMANCE TEST RESULTS

The performance data supporting substantial equivalence of the LenSx 550 femtosecond laser system to the predicate devices are summarized as follows:

- Pre-clinical studies applying the LenSx phacofragmentation pattern in plastic substrates demonstrated a high degree of accuracy and reproducibility for laser pulse placement.
- LenSx phacofragmentation performed in *ex vivo* porcine eyes further confirmed the accuracy and reproducibility of the localized laser tissue effects. This testing also demonstrated that the ultrasound power required to complete the phacofragmentation procedure was significantly reduced in comparison to procedures performed using standard phacofragmentation and phacoemulsification techniques with the Alcon Series 20000 Legacy, the most common such device.
- A prospective clinical study was performed outside the U.S. to evaluate clinical performance, with a total of 92 subjects randomly assigned to one of the following treatment groups:
 1. A study group of 46 eyes underwent initial laser phacofragmentation using the LenSx 550 Laser, followed by phacoemulsification using the Alcon Series 20000 Legacy.
 2. A control group of 46 eyes underwent phacofragmentation and phacoemulsification with the Alcon Series 20000 Legacy (predicate device), using a surgical technique previously demonstrated to significantly reduce ultrasound power requirements.

Compared to the control group where only standard ultrasonic phacoemulsification was used, the study group (using laser phacofragmentation) required significantly less manual manipulation and ultrasound power to achieve the desired phacofragmentation effect. Clinical results were excellent in both groups, with no significant adverse events. Results in both groups were consistent with those of advanced phacoemulsification techniques reported in previous studies (Can, 2004).



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

APR 23 2010

LenSx Lasers, Incorporated
c/o Judy F. Gordon, D.V.M.
ClinReg Consulting Services, Inc.
733 Bolsana Drive
Laguna Beach, California 92651

Re: K094052

Trade/Device Name: LenSx 550 Laser System, Model 550
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE, HQC
Dated: March 23, 2010
Received: March 25, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

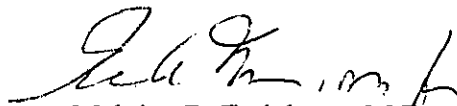
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/MedicalDevices/Safety/ReportaProblem/default.htm> 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/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

510(k) Number (if known): _____

Device Name(s): LenSx 550 Laser System

Indications for Use:

The LenSx 550 Laser System is indicated for anterior capsulotomy and laser phacofragmentation during cataract surgery. The anterior capsulotomy and phacofragmentation procedures may be performed either individually or consecutively during the same 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)

Page 1 of 1

Daryl Kaubman, M.A.
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K094052