OCT 19 2011

K112098

510(K) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS (SS&E)

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:
LensAR, Inc.
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Orlando, FL 32826
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b. Contact Person:
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DATE SUMMARY PREPARED: July 20, 2011

NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME

a. Trade/Proprietary Name: LensAR-fs Laser System
b. Common/Usual Name: LensAR-fs Laser System
c. Classification Name: Ophthalmic Laser, Phacofragmentation System
d. Classification Code(s): 21 CFR 886.4390 OOE; 21 CFR 886.4670 HQC

PREDICATE DEVICES

510(K) #	TRADE NAME	MANUFACTURER
K090633 and K102727	LensAR Laser System	LensAR, Inc.
K094052 and K082947	LenSx 550 Laser System Model 550	LenSx Lasers, Inc.

DEVICE DESCRIPTION

The predicate LensAR Laser System is an ophthalmic surgical laser that has been cleared for use in anterior capsulotomy in cataract surgery (K090633) and anterior capsulotomy and laser phaco fragmentation performed individually or consecutively during the same surgery (K102727). A new laser device with modification to the pulse width of the laser (LensAR-fs Laser System) is intended for use in the same indication as cleared in K102727.

The system employs a mode-locked Yb:YAG laser which generates a high frequency series of ultrashort (1500 femtosecond), low energy pulses at a wavelength of 1030 nm. The system is technologically the same as defined for the predicate device, i.e., designed to cut the lens and lens capsular tissue, with minimal collateral damage, by the mechanisms of plasma mediated ablation and photodisruption of targeted tissue at the beam focus. The precision capsulotomy and lens fragmentation is generated by computer-controlled scanning of the position of the laser beam focus in three dimensions at the target location. The laser energy is delivered to the eye through a disposable, patient interface device that consists of two separately packaged parts: a commercially available Suction Ring with Spring Loaded Syringe to fixate the eye and an Index Matching Eye Docking (IMED) device designed to match the refractive index of the cornea to optimize beam targeting accuracy.

STATEMENT OF INTENDED USE

The LensAR-fs Laser System is indicated for anterior capsulotomy and laser phaco fragmentation during cataract surgery. The anterior capsulotomy and laser phaco fragmentation procedures may be performed either individually or consecutively during the same surgery.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The LensAR-fs Laser System is consistent with the technological characteristics of the predicate device LensAR Laser for use in Anterior Capsulotomy (K090633) and in Laser Phaco Fragmentation (K102727). This LensAR-fs Laser surgical device incorporates a change in pulse width and minor software and hardware changes for use in the same Indications for Use: Anterior Capsulotomy and Laser Phaco Fragmentation during cataract surgery.

The LensAR-fs Laser System is of comparable type and is substantially equivalent to the following predicate devices:

510(k) Number	Clearance Date	Device Description
K102727 Anterior Capsulotomy & Laser Phaco Fragmentation K090633 Anterior Capsulotomy	03/16/2011 05/13/2010	LensAR Laser System – Laser Technology and Indications for Use predicate device
K094052 Anterior Capsulotomy & Lens Fragmentation K082947 Anterior Capsulotomy	04/23/2010 08/14/2009	LenSx 550 Laser System - Laser Technology and Indications for Use predicate device

- The activities used to evaluate the LensAR-fs Laser System (LLS-fs) and the information and reports provided in this 510(k) submission do not identify any new issues of safety or effectiveness. The optical radiation hazard analysis done by Dr. Sliney confirms the continuing ocular safety equivalence to the predicate device detailed in 510(k) K102727 for the predicate device.
- The LensAR-fs Laser technology and mechanism of laser-tissue interaction are similar to other ultrashort pulse lasers identified in the table above.
- The indication for use statement for anterior capsulotomy and laser phaco fragmentation for the LLS-fs is the same as that of the predicate devices detailed in the table above.
- The differences between the LLS-fs and the predicate devices are insignificant and do not affect the safety or effectiveness of the device.

BRIEF SUMMARY OF PRECLINICAL AND CLINICAL PERFORMANCE TEST RESULTS

The performance data supporting substantial equivalence of the LensAR-fs Laser System to the predicate LensAR device are summarized as follows:

Summary of Pre-Clinical Testing

Testing and analyses performed included accuracy and reproducibility of capsulotomy incisions in ex vivo porcine eyes. The data demonstrated that the LensAR-fs Laser produces anterior capsulotomy incision patterns that are accurate and predictable in size and shape, which confirm equivalence to those achieved with the predicate LensAR Laser device (K090633 and K102727).

Additional evaluations were done in human donor ocular globes to establish the equivalence of the geographical cutting patterns to those established for the predicate LensAR Laser in 510(k) K102727. In the same manner, as demonstrated by the LensAR predicate device use, the fs laser causes the lens to be divided, employing linear cuts, into a number of radial sections, similar in shape to those created by the conventional manual "phaco chop" surgical technique, and then further divided by applying a set of concentric cylindrical cuts through the radial sections.

The technical characteristics of the LensAR-fs Laser fall between those of the LensAR Laser and the LenSx Laser as seen in the comparative analysis supplied in the supporting documentation and raise no new issues with respect to the safety and effectiveness of the device in its intended use. Thus no new clinical evaluations were required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 19 2011

LensAR, Inc.
c/o Ms. Shirley McGarvey
Regulatory Consultant
2800 Discovery Drive, Suite 100
Orlando, FL 32826

Re: K112098
Trade/Device Name: LensAR-fs Laser System for Anterior Capsulotomy and Laser Phaco Fragmentation
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE, HQC
Dated: September 27, 2011
Received: September 29, 2011

Dear Ms. McGarvey:

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.

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,

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

Indications for Use Statement

510(k) Number (if known): K112098

Device Name: LensAR-fs Laser System for Anterior Capsulotomy and Laser Phaco Fragmentation

Indications for Use: The LensAR-fs Laser System is indicated for anterior capsulotomy and laser phaco fragmentation during cataract surgery. The anterior capsulotomy and laser phaco fragmentation procedures may be performed either individually or consecutively during the same surgery.

Prescription Use: X And/Or Over-the-Counter Use: _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jon C Callaway for DLK
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K112098