

MAR 16 2011

**PREMARKET NOTIFICATION 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: LensAR, Inc.  
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Orlando, FL 32826  
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- b. Contact Person: S.K. McGarvey  
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**DATE SUMMARY PREPARED:** December 20, 2010

**NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME**

- a. Trade/Proprietary Name: LensAR Laser System
- b. Common/Usual Name: LensAR Laser System
- c. Classification Name: Ophthalmic Laser, Phacofragmentation System
- d. Classification Code(s): 21 CFR 886.4392 OOE; 21 CFR 886.4390 OOE;  
21 CFR 886.4670 HQC

**PREDICATE DEVICES**

510(K) #	TRADE NAME	MANUFACTURER
K090633	LensAR Laser System for Anterior Capsulotomy	LensAR, Inc.
K094052 and K082947	LenSx 550 Laser System Model 550	LenSx Lasers, Inc.
K021566 and K082845	Infiniti Cataract Extraction System	Alcon Laboratories, Inc.

**DEVICE DESCRIPTION**

The LensAR Laser System is an ophthalmic surgical laser that has already been cleared for use in anterior capsulotomy in cataract surgery (K090633). It is now intended for additional use in anterior capsulotomy and laser phacofragmentation in cataract surgery, performed individually or consecutively during the same surgery.

The LensAR Laser generates ultrashort laser pulses that are scanned in a three-dimensional pattern in the eye to cut the anterior capsulotomy and to pre-cut the lens into small pieces for easy removal by conventional ultrasound phaco fragmentation. The fragmentation pattern is customized to the patient's eye based on precise measurement of the size, shape and position of the patient's lens by a built-in optical measuring system. During the measurement and subsequent application of the laser pulses, the eye is positioned and immobilized by an off-the-shelf suction ring assembly which is affixed to the eye and which is in turn docked to a refractive index matching eye docking (IMED) device mounted to the laser system.

**STATEMENT OF INTENDED USE**

The LensAR 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 Laser System proposed for use in phacofragmentation is identical with respect to all technological characteristics to the previously cleared LensAR for use in anterior capsulotomy (K090633). Substantial equivalence is also drawn to previously cleared phacofragmentation systems.

As described in K090633, anterior capsulotomy is performed by delivering a cylindrical pattern of laser pulses to intersect the anterior lens capsule. In the laser phaco fragmentation procedure, the lens is divided into a number of radial sections, similar in shape to those created by the conventional manual "phaco chop" technique (Chop), and then further divided by applying a set of concentric cylindrical cuts through the radial sections (Cylinder).

Following the laser procedure and entry into the eye by conventional means, the fragmented nuclear sections created by the LensAR Laser are further fragmented by ultrasound if necessary, and removed using a standard phacoemulsification probe and aspiration.

Predicate devices include laser and ultrasound phacoemulsification devices cleared for phacofragmentation, such as the Alcon Series Infiniti System (Alcon Laboratories, Inc., K021566 and K082845) and the LenSx Laser 550 (K082947 and K094052). 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. The LenSx Laser works in the same technical manner as that described above for the LensAR device.

The LensAR Laser's ultrashort, photo disruptive pulses are of sufficiently low energy that the system can accomplish phaco fragmentation while transmitting to surrounding tissue only a tiny fraction of the ultrasonic shockwaves/energy generated by handheld ultrasound phaco fragmentation probes. The laser treatment is applied directly to the crystalline lens through the cornea without the necessity of creating an external wound.

#### **BRIEF SUMMARY OF PRECLINICAL AND CLINICAL PERFORMANCE TEST RESULTS**

The performance data supporting substantial equivalence of the LensAR Laser system to the predicate devices are summarized as follows:

##### **Summary of Pre-Clinical Testing**

Testing and analyses performed included accuracy and reproducibility of capsulotomy and laser phaco fragmentation incisions in porcine eyes and plastic substrates. The data demonstrated that the LensAR produces anterior capsulotomies and laser phaco fragmentation incision patterns that are accurate and predictable in size and shape. Additional safety testing comparing the acoustic and thermal characteristics of the device to predicate ultrasound phaco emulsification devices demonstrated a safe operating profile with respect to these parameters. Evaluation on *ex vivo* porcine eyes confirmed the safety with respect to corneal endothelium.

##### **Summary of Clinical Studies**

A prospective clinical study was performed outside the U.S. to evaluate clinical performance. A total of 88 subjects were treated with either a laser anterior capsulotomy/laser lens fragmentation, or a laser fragmentation/manual continuous curvilinear capsulorhexis (CCC), followed if needed by further standard ultrasound lens fragmentation and then irrigation aspiration of the lens in one eye. The eye selection in each patient was the one having the worse cataract condition. In patients needing bilateral cataract removal, the contralateral (fellow eye) of the patient was treated with conventional CCC and ultrasound phacofragmentation at some point after the first eye surgery.

The Primary cohort underwent initial laser phacofragmentation or laser anterior capsulotomy and phacofragmentation using the LensAR Laser, followed if needed by phacoemulsification using ultrasound with the Alcon Series Infiniti System.

A Control Cohort of contralateral eyes in these subjects underwent CCC/phacofragmentation and phacoemulsification with the Alcon Infiniti (predicate device), using a torsional mode, a method demonstrated in the literature to significantly reduce ultrasound power requirements as compared to earlier ultrasound longitudinal devices.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room – WO66-0609  
Silver Spring, MD 20993-0002

LensAR, Inc  
c/o Ms. Shirley McGarvey  
Regulatory Consultant for LensAR, Inc  
210 North Park Ave.,  
Winter Park, FL 32789

MAR 16 2011

Re: K102727

Trade/Device Name: LensAR 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: February 2, 2011

Received: February 3, 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.

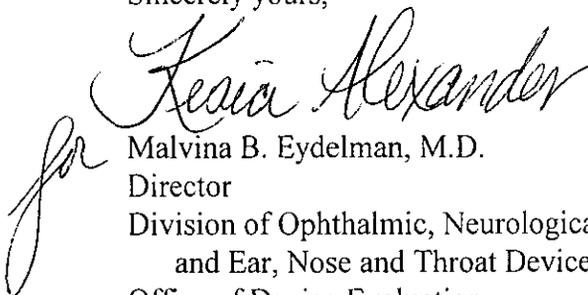
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "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,

A handwritten signature in cursive script that reads "for Malvina B. Eydelman". The word "for" is written vertically to the left of the main signature.

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):** K102727

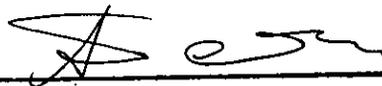
**Device Name:** LensAR Laser System for Anterior Capsulotomy and Laser Phaco Fragmentation

**Indications for Use:** The LensAR 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)**



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

510(k) Number K102727