510(K) SUMMARY

DEC 3 2012

This 510(k) summary 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

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DATE SUMMARY PREPARED: September 14, 2012

NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME

a. Trade/Proprietary Name: LensAR Laser System - fs 3D (LLS-fs 3D)
b. Common/Usual Name: LensAR Laser System - fs 3D (LLS-fs 3D)
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
K120214	LensAR Laser System – fs 3D	LensAR, Inc.
K101626	LenSx 550 Laser System	LenSx Lasers, Inc. (Alcon)

DEVICE DESCRIPTION

The predicate LensAR Laser System is an ophthalmic surgical laser that has been cleared by the Agency for use in anterior capsulotomy and laser phaco fragmentation in cataract surgery performed individually or consecutively during the same surgery under K120214 (LensAR Laser System - fs 3D).

The current LLS-fs 3D uses the same laser and the same beam guidance system to deliver laser pulses to the eye as the predicate LensAR device cleared via 510(k) K120214. Also, the patient interface device (PID), controlled force docking mechanism and moveable

optical head to dock the laser to the stationary patient are unchanged from that described in 510(k) K120214. The Indication for Use is now expanded to include creation of the incisions for entry to the eye in cataract surgery.

The LLS-fs 3D biometric system, which measures and constructs a three dimensional model of the optical surfaces within the eye, is unchanged from the predicate device except for software modifications to allow the system to analyze the shape and position of the peripheral cornea.

STATEMENT OF INTENDED USE

The LensAR Laser System - fs 3D (LLS-fs 3D) is intended for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, laser phacofragmentation, and the creation of single-plane and multi-plane cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The femtosecond laser system, including pulse energy control and monitoring, used in the current LLS-fs 3D is the same as that used in the predicate device cleared in K120214. The primary difference between the current LensAR Laser System – fs 3D device and the predicate device is the addition of software for the indication of single-plane and multi-plane cuts/incisions in the cornea for cataract surgery.

In the predicate device, the biometric system measured the shape and position of the central cornea for use in the ray tracing necessary to correctly place laser incisions within the crystalline lens. In the current device, corneal measurements are also used to generate custom shot patterns for the corneal incisions.

The LLS-fs 3D is of comparable type and is substantially equivalent to the following predicate devices:

510(k) Number	Clearance Date	Device Description
K120214	06/08/2012	LensAR Laser System – fs 3D (LLS-fs 3D) for anterior capsulotomy and laser phacofragmentation
K101626	10/18/2010	LenSx Laser System for anterior capsulotomy, phacofragmentation, and creation of single-plane and multi-plane arc cuts/ incisions in the cornea

- The activities used to evaluate the LensAR Laser System - fs 3D (LLS-fs 3D) 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 confirms the continuing ocular safety and the equivalence to the predicate device detailed in 510(k) K120214.

- The LLS-fs 3D laser technology and mechanism of laser-tissue interaction are unchanged from that of the femtosecond laser cleared under K120214.
- The indication for use statement for anterior capsulotomy and laser phacofragmentation for the LLS-fs 3D is the same as that of the predicate devices detailed in the table above and the indication for use statement for incisions of the cornea in cataract surgery is the same as the LenSx laser (K101626).
- The differences between the modified LLS-fs 3D and the predicate devices are insignificant and do not affect the safety or effectiveness of the device.

BRIEF SUMMARY OF PERFORMANCE TEST RESULTS

The performance data supporting substantial equivalence of the LensAR Laser System - fs 3D to the predicate LensAR device is summarized as follows:

- An analysis of the optical radiation hazard to non-target tissue demonstrated that the current LLS-fs 3D femtosecond laser, biometric system scanning diode light source, and patient eye illumination (light emitting diodes) are eye safe under all normal operating and known fault conditions.
- Evaluation of the accuracy and reproducibility of the locations and geometry of laser vs. manual planar corneal cuts/incisions showed the mean incision length for the laser incision was statistically significantly closer to the target length than was the case for the manual CCIs. In addition, the variance of the angles of the entrance and exit planar incisions relative to the corneal surface showed that the laser incisions had statistically significantly lower variance for these geometry parameters compared to the manual incisions.
- Evaluation of the effect of the laser vs. manual incisions at the corneal periphery on endothelial cells of ex vivo porcine eyes showed that the laser method resulted in statistically smaller percentage losses compared to that of the manual incision method when the exit of the incision was normal to the surface but not significantly different when the exit incision geometry was at 45° to the surface.
- Evaluation of the incision seal integrity and wound structure after the laser vs. manual incision for cataract surgery showed there was no difference in susceptibility to leakage between the two types of incisions. Overall, the testing showed that the manual and laser methods are statistically equivalent in sealability but that the laser method produces more consistent wound geometry.
- A hazard analysis of all potential hazards to the patient, surgeon and other system operators was performed to consider all changes between the current LLS-fs 3D and predicate LLS-fs 3D device. The hazard analysis demonstrates that all potential hazards have acceptable levels of probability/severity characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 3, 2012

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

Re: K122829
Trade/Device Name: LensAR Laser System – fs 3D (LLS-fs 3D)
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: II
Product Code: HQC
Dated: September 14, 2012
Received: September 17, 2012

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 (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/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 Y. Alexander

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known): K122829

Device Name: LensAR Laser System - fs 3D (LLS-fs 3D)

Indications for Use: The LensAR Laser System - fs 3D (LLS-fs 3D) is intended for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, laser phacofragmentation, and the creation of single-plane and multi-plane cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

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)

Daniel Kaufman, MA

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

510(k) Number K122829