K120732

SEP 6 2012

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:
Alcon LenSx, Inc.
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b. Contact Person:
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c. Date: August 8, 2012

NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME

a. Trade/Proprietary Name: LenSx Laser System
b. Common/Usual Name: LenSx Laser System
c. Classification Name: Laser Instrument, Surgical, Powered
d. Classification Code(s): 21 CFR 886.4390; OOE, HQC, HNO

PREDICATE DEVICES

510(K) #	TRADE NAME	MANUFACTURER
K101626	LenSx Laser System	LenSx Lasers, Inc. (now Alcon LenSx, Inc.)
K993153 K041893 K060372 K073404	IntraLase Laser	IntraLase Corp. (now Abbot Medical Optics, Inc.)
K101006	WaveLight FS 200 Laser System	Alcon Research, Ltd.
K033354	Femtec Laser Microkeratome	20/10 Perfect Vision OPtische Gerate GmbH
K100253	Visumax Laser Keratome	Carl Zeiss Meditec

DEVICE DESCRIPTION

The LenSx Laser System uses focused femtosecond laser pulses to create incisions and separates tissue in the lens capsule, crystalline lens, and the cornea. Individual photodisruption locations are controlled by repeatedly repositioning the laser focus. 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 incisions or tissue separation.

The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target 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 a sterile, disposable applanating lens and suction ring assembly that contacts the cornea and fixes the eye with respect to the delivery system.

The LenSx Laser System proposed in this 510(k) premarket notification is a modification of the previously cleared LenSx Laser System, manufactured by Alcon LenSx, Inc. (K101626). It is essentially the same laser system with the addition of a new indication for use, namely the creation of a corneal flap in patients undergoing LASIK surgery or other treatments requiring initial lamellar resection of the cornea. This same indication has been cleared for use with multiple predicate femtosecond laser devices since 1999, including the IntraLase Laser (K993153, K041893, K060372, and K073404), the WaveLight FS 200 Laser System (K101006), the Femtec Laser Microkeratome (K033354), and the Zeiss Visumax Laser Keratome (K100253). Femtosecond lasers now perform the majority of LASIK flaps in the United States and virtually all those performed by the US Armed Forces, with numerous articles documenting their use and advantages.[6,7,8]

STATEMENT OF INTENDED USE

The LenSx Laser System is indicated for use:

- In the creation of corneal cuts/incisions, anterior capsulotomy and laser phacofragmentation during cataract surgery. Each of these procedures may be performed either individually or consecutively during the same surgery.
- In the creation of a lamellar cut/resection for lamellar keratoplasty, and in the creation of a penetrating cut/incision for penetrating keratoplasty
- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea

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[6] Panday VA, Reilly CD. Refractive surgery in the United States Air Force. Current Opinion in Ophthalmology 2009, 20:242-246.

[7] Kim P, Sutton GL, Rootman DS. Applications of the femtosecond laser in corneal refractive surgery. Current Opinion in Ophthalmology 2011, 22:238-244.

[8] Duffey RJ, Leaming D. US Trends in Refractive Surgery: The 2009 ISRS Survey.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The LenSx Laser System is essentially the same device as the predicate LenSx Laser System with modifications made to improve usability and manufacturability. These modifications include:

- Software updates to allow for the additional corneal flap pattern
- An increase in the laser repetition rate from 33 kHz to 150 kHz for the flap pattern with maximum possible average power of 1 Watt.
- An increase in the laser repetition rate from 33 kHz to 50 kHz for patterns used for the previously cleared indications in cataract and keratoplasty surgery with maximum possible average power of 1 Watt.
- Extension of shelf-life to 24 months for the sterile disposable patient interface.
- Updated user labeling that describes the above changes, as well as changes to the graphical user interface to improve usability.

BRIEF SUMMARY OF PERFORMANCE TEST RESULTS

The performance data supporting substantial equivalence of the LenSx Laser with the above modifications include:

- Evaluation of the accuracy and reproducibility of the depths and geometry of each of the previously cleared treatment patterns, as well as energy stability using the modified LenSx Laser in comparison to acceptance criteria established for the predicate LenSx Laser
- Evaluation of the accuracy and reproducibility of the depths and geometry and surface quality of lamellar resections using the same parameter acceptance criteria.

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

SEP 6 2012

Alcon LenSx, Incorporated
% Ms. Judy Gordon, D.V.M.
ClinReg Consulting Services, Inc.
Regulatory Consultant to Alcon LenSx, Inc.
733 Bolsana Drive
Laguna Beach, CA 92651

Re: K120732
Trade/Device Name: LenSx® Laser system
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: OOE, HQC, HNO
Dated: August 8, 2012
Received: February 23, 2012

Dear Ms. 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.

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

510(k) Number (if known): K120732

Device Name(s): LenSx Laser System

Indications for Use:

The LenSx Laser System is indicated for use:

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- In the creation of a lamellar cut/resection for lamellar keratoplasty, and in the creation of a penetrating cut/incision for penetrating keratoplasty.
- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

M L Burke Nicholas

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

510(k) Number K120732

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)