DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 16, 2016

Alcon Laboratories, Inc.
Mr. James Arganda
Director Global Regulatory Affairs Projects
20511 Lake Forest Drive
Lake Forest, CA 92630

Re: K161288
Trade/Device Name: Lensx Laser System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE
Dated: October 11, 2016
Received: October 12, 2016

Dear Mr. Arganda:

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 contact the Division of Industry and Consumer Education 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.
Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161288/S002

Device Name
LenSX Laser System

Indications for Use *(Describe)*

• In the creation of corneal cuts/incisions (single-plane, multi-plane and arcuate), 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 corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter of the 510(k)

Company:	Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX USA 76134-2099
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Back up Contact Person:	Bob Lundberg Alcon LenSx, Inc. 20511 Lake Forest Dr. Lake Forest, CA 92630
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Date Prepared:	July 11, 2016

Device Names

Common Name:	LenSx Laser System
Trade/Proprietary Name:	LenSx Laser System
Classification Name:	Ophthalmic Femtosecond Laser
Device Classification:	21 CFR 886.4390; OOE, HQC, HNO

Predicate Devices

510(k) #	Trade Name	Manufacturer
Laser System		
K101626 K120732 K123120	LenSx Laser System	Alcon LenSx, Inc.
Patient Interface Accessories		
K101626 K120732	LenSx Laser Patient Interface	Alcon LenSx, Inc.
K123120	LenSx Laser SoftFit Patient Interface	Alcon LenSx, Inc.

Description of Device:

The LenSx Laser System is an ophthalmic surgical laser which uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea. A femtosecond light pulses 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. A computer-controlled scanning system directs the focused laser beam throughout a three-dimensional pattern to produce an incision. The surgical effect is produced by scanning thousands of individual pulses per second to produce a continuous incision or tissue separation.

The laser pulses are delivered through a Patient Interface accessory that is placed on the surface of the cornea and fixes the position of the eye with respect to the delivery system. Two models of the Patient Interface accessory are offered for use with the LenSx Laser System: the LenSx Laser Patient Interface and the LenSx SoftFit Patient Interface. Both models consist of a sterile, disposable applanating lens and suction ring assembly that contacts the cornea and fixes the eye with respect to the delivery system. In addition, LenSx SoftFit Patient Interface model comes with a soft contact lens that is positioned against the internal surface of the patient Interface glass. For cataract procedures, the LenSx SoftFit Patient Interface is used. For corneal flap procedures, the LenSx Laser Patient Interface is used.

Indications for Use:

The LenSx Laser System is indicated for use:

- In the creation of corneal cuts/incisions (single-plane, multi-plane and arcuate), 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 corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea

Description of Safety and Substantial Equivalence:

The subject of this Traditional 510(k) premarket notification is the software and hardware modifications to the LenSx Laser System and the removal of the indication for lamellar keratoplasty from the Indications for Use statement. All modifications were tested to show substantial equivalence to the predicate devices and do not alter the safety and effectiveness of the devices.

The LenSx Laser System is essentially the same device as the predicate LenSx Laser System. These modifications are categorized as follows:

- Hardware updates to improve manufacturability and serviceability. Hardware modifications to implement switchable laser operation at 50 or 150 kHz.

- Software updates to implement the use of a planner Ethernet device for cataract surgery, re-enabling flap functionality that was previously cleared, and introducing an optional lens fragmentation pattern whose parameters are within previously cleared treatment ranges.

- Labeling updates to the operator's manual to reflect the implementation of the changes described above.

- A revised Indications for Use statement that removes the indication for lamellar keratoplasty.

- Extension of shelf-life to two (2) years for the sterile disposable LenSx Laser SoftFit Patient Interface.

All modifications were tested to show substantial equivalence to the predicate devices and do not alter the safety and effectiveness of the devices. **Table A** summaries the substantial equivalence between the modified device and the predicate devices.

Table A: Substantial Equivalence Comparison

	Modified Device	Predicate Device
	LenSx Laser System	**LenSx Laser System**
510(k) number:	K161288	K101626, K120732, K123120
Indications for Use:	The LenSx Laser System is indicated for use: • In the creation of corneal cuts/incisions (single-plane, multi-plane, and arcuate), 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 corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.	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.
Operating Principle	Femtosecond laser photodisruption	Femtosecond laser photodisruption
Mechanism of Action	Cutting and resection surfaces are created by scanned patterns of femtosecond laser micro-photodisruptions in tissue.	Cutting and resection surfaces are created by scanned patterns of femtosecond laser micro-photodisruptions in tissue.

Performance Data

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 using the modified LenSx Laser in comparison to acceptance criteria established for the predicate LenSx Laser.

- Evaluation of the accuracy and reproducibility of energy stability using the modified LenSx Laser in comparison to acceptance criteria established for the predicate LenSx Laser.

Non-clinical Testing:

Successful verifications and process validations were performed on the modified device demonstrating equivalence to the predicate devices for the creation of corneal flaps, and for the creation of phacofragmentation patterns including lens fragmentation, capsulotomy treatments and corneal incision/cuts. Additionally, successful verification was performed on the modified device to verify the accuracy and reproducibility of laser energy at laser repetition rates of 150 kHz and 50 kHz. Finally, all hardware modifications were verified to demonstrate equivalence to the predicated device.

Non-clinical performance testing demonstrated that:

- The modified LenSx Laser delivers a high degree of accuracy and reproducibility for the creation of corneal flaps suitable for LASIK compared to the predicate devices.
- The modified LenSx Laser delivers a high degree of accuracy and reproducibility for the creation of phacofragmentation patterns, including lens fragmentation treatments, capsulotomy treatments and corneal incisions/cuts.
- The modified LenSx Laser delivers a high degree of accuracy and reproducibility in the generation of laser pulse energies up to 2.6 μJ (for 150 kHz) and 15 μJ (for 50 kHz).
- Hardware modifications were verified to demonstrate equivalence of the modified device to the predicate devices. All hardware modifications met required verification criteria.

Clinical Testing:

The scope of the software and hardware modification did not require clinical testing to establish safety and effectiveness of the modified device.

Conclusions

The subject of this Traditional 510(k) premarket notification is the hardware and software modifications to the LenSx Laser System, the extension of shelf life for the LenSx Laser SoftFit Patient Interface, the removal of the indication for lamellar keratoplasty from the Indications for Use statement, and labeling changes to support

these modifications. All hardware and software modifications to the LenSx Laser System were tested to show substantial equivalence to the predicate devices and do not alter the safety and effectiveness of the devices.

With the exception of the removal from the indication for use for the creation of a cut/resection for lamellar keratoplasty, the modified device in this 510(k) is substantially equivalent to the predicate devices.