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

February 3, 2017

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

Re: K163551
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: December 13, 2016
Received: December 19, 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,

Denise L. Hampton -S

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)*
K163551

Device Name
LenSx Laser System

Indications for Use *(Describe)*

The LenSx Laser 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.

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

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

### 1. Submitter


| | |
|---|---|
| Applicant: | Alcon Laboratories, Inc.<br>6201 South Freeway<br>Fort Worth, TX 76134-2099 |
| Contact Person: | James Arganda<br>Alcon Research, Ltd.<br>20511 Lake Forest Dr.<br>Lake Forest, CA 92630<br>james.arganda@alcon.com<br>Tel: (949) 505-7038<br>Fax: (949) 505-6237 |
| Date Prepared: | February 2, 2017 |


### 2. Device

| | |
|---|---|
| Trade/Proprietary Name: | LenSx Laser System |
| Common/Usual Name: | Femtosecond laser system |
| Classification Name: | Laser Instrument, Surgical, Powered |
| Regulatory Class: | II |
| Classification Code(s): | 21 CFR 886.4390; OOE, HQC, HNO |

## 3. Predicate Device

LenSx Laser System, K161288

## 4. Device Description

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. The LenSx SoftFit Patient Interface model is offered with three different sizes of soft contact lenses that are 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.

## 5. Indications for Use

The following indications for use for the LenSx Laser System are unchanged from the previously cleared device (K161288):

- 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.

## 6. Technological Characteristics Comparison

The subject of this 510(k) Premarket Notification is the offering of two additional sizes of the soft contact lens insert used with the SoftFit Patient Interface accessory that is currently sold for use with the LenSx Laser System. These additional sizes are being offered to better accommodate variations in corneal curvature and enhance patient comfort during docking of the laser objective prior to treatment. The original universal size (nominal) remains unchanged with a central base curve of 7.6 mm. The additional sizes will include:

- a contact lens insert with a central base curve of 7.2 mm for steeper corneas with an average K-reading greater than >46 D; and
- a contact lens insert with a central base curve of 8.1 mm for flatter corneas with an average K-reading of <41 D.

All three SoftFit inserts will be used with the existing LenSx Laser SoftFit Patient Interface Cone.

There are no changes to the LenSx Laser System hardware or software. There are no changes to intended use, the indications for use, or product claims of the LenSx Laser System as a result of the proposed change.

All modifications were tested to show substantial equivalence and were as safe and effective as the predicate device. The following summarizes the substantial equivalence between the modified device and the predicate device.

**TECHNOLOGICAL COMPARISON OF THE ORIGINAL SOFTFIT INSERT AND THE PROPOSED SOFTFIT INSERTS**

| | LenSx® LASER SYSTEM K161288 PREDICATE | LenSx® LASER SYSTEM PROPOSED |
|---|---|---|
| **Trade Name** | LenSx® Laser System, | LenSx® Laser System |
| **Indication for Use** | The LenSx Laser System is indicated for use:<br>• 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.<br>• In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea | Same |
| **Contact Lens Material** | efrofilcon A, 74% water | Same |
| **Sizes Available** | Nominal | Nominal<br><41 D<br>>46 D |
| **Method of Sterilization** | Steam Autoclave | Same |
| **Use** | Single Use | Same |

## 7. Brief Summary of Performance Test Results

The performance data supporting substantial equivalence of the SoftFit Patient Interface accessory includes evaluation of the accuracy and reproducibility of the depths and geometry of each of the previously cleared cataract treatment patterns for the LenSx Laser when the SoftFit Patient Interface is used with the new insert sizes.

## 8. Conclusions

The subject of this 510(k) Premarket Notification is the addition of two new SoftFit Insert sizes and the labeling and risk analysis changes to support these additional models. Performance testing on the new sizes show that the device is as safe and as effective as the predicate device.