March 27, 2018

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

Re: K173660
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: February 15, 2018
Received: February 16, 2018

Dear James 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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
Indications for Use

510(k) Number (if known)
K173660

Device Name
LenSx Laser System

Indications for Use (Describe)

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.

- In the creation of corneal pockets for placement/insertion of a corneal inlay device and for creation of corneal tunnels for the placement of corneal rings.

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 document has been prepared in accordance with section 21 CFR 807.92.

I. Submitter of the 510(k)

Company: Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099, USA

Primary Contact Person: James Arganda
Alcon Research, Ltd.
20511 Lake Forest Dr.
Lake Forest, CA 92630

Phone: (949) 505-7038
Fax: (949) 505-6237
Email: james.arganda@alcon.com

Back up Contact Person: Kim Regis
Phone: (949) 505-7232
Fax: (949) 505-6237
Email: kim.regis@alcon.com

Date Prepared: 28 November 2017

II. Devices Subject to this 510(k)

Trade/Device Name: LenSx Laser System

Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Device Classification: Class II
Product Code: OOE, HQC, HNO
III. Predicate Device

<table>
<thead>
<tr>
<th>510(k) Clearance</th>
<th>Primary Predicate Device</th>
<th>Additional Predicates</th>
</tr>
</thead>
<tbody>
<tr>
<td>K163551</td>
<td>K141852</td>
<td>K141476</td>
</tr>
</tbody>
</table>

Device Name

<table>
<thead>
<tr>
<th>Manufacture</th>
<th>LenSx Laser System</th>
<th>iFS Laser System</th>
<th>WaveLight FS200</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcon Laboratories, Inc.</td>
<td>AMO Manufacturing USA, LLC</td>
<td>Alcon Laboratories, Inc.</td>
<td></td>
</tr>
</tbody>
</table>

IV. 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 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.

V. Indications for Use

The following indications for use for the LenSx Laser System are unchanged from the previously cleared device (K163551):

• 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.

• In the creation of corneal pockets for placement/insertion of a corneal inlay device; and for creation of corneal tunnels for the placement of corneal rings.

VI. Comparison to Technological Characteristics with the Predicate Device

The modified LenSx Laser System is substantially equivalent to the primary predicate device (K163551) and additional predicate devices (K141852, K141476) in terms of indications for use, technological characteristics and fundamental scientific technology. The subject and predicate laser systems share the same design principle and mode of operation in that they all deliver femtosecond pulses through a computer-controlled delivery system to produce a pattern of photodisruption to create incisions in the ophthalmic tissue. The means of fixation of the patient contact portion of the devices are all substantially equivalent in that the suction vacuum affixes a suction ring to the corneal surface prior to use.

No changes to the LenSx Laser System’s operating principles, system specifications or disposable Patient Interface were required to support the additional indications for use. Software updates were implemented to support the new functionality along with associated graphical user interface functionality. While no changes are proposed to the LenSx Laser system hardware, new painted skin colors that are intended to harmonize the appearance of the LenSx Laser console appearance with other Alcon commercial products are proposed.

Modifications proposed in this 510(k) premarket notification were tested to show substantial equivalence to the predicate device. The following summarizes the substantial equivalence between the modified device and the predicate device.
<table>
<thead>
<tr>
<th>Indication for Use</th>
<th>510(k) Clearance</th>
<th>Device Name</th>
<th>Primary Predicate</th>
<th>Additional Predicate</th>
<th>Additional Predicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>The LenSx Laser System is indicated for use:</td>
<td>K163551</td>
<td>LenSx Laser System</td>
<td>K141852</td>
<td>K141476</td>
<td></td>
</tr>
<tr>
<td>□ In the creation of corneal cuts/incisions (single-plane, multi-plane, and arcuate), anterior capsulotomy and laser phacoemulsification during cataract surgery. Each of these procedures may be performed either individually or consecutively during the same surgery.</td>
<td></td>
<td>LenSx Laser System</td>
<td>iFS Laser System</td>
<td>WaveLight FS200</td>
<td></td>
</tr>
<tr>
<td>□ In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea</td>
<td></td>
<td>Alcon Laboratories</td>
<td>AMO Manufacturing USA, LLC</td>
<td>Alcon Laboratories</td>
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<td>□ In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea</td>
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<tr>
<td>□ In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments</td>
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<tr>
<td>□ In patients undergoing ophthalmic surgery or other treatment requiring arcuate cuts/incisions in the cornea, penetrating and/or intrastromal</td>
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</tr>
</tbody>
</table>

The WaveLight FS200 Laser System is an ophthalmic surgical laser indicated for use:
- □ In the creation of a corneal flap in patients undergoing LASIK surgery or other surgery or treatment requiring initial lamellar resection of the cornea.
- □ In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments.
- □ In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments.
<table>
<thead>
<tr>
<th>SYSTEM PROPOSED</th>
<th>PRIMARY PREDICATE</th>
<th>ADDITIONAL PREDICATE</th>
<th>ADDITIONAL PREDICATE</th>
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</thead>
</table>
| lamellar resection of the cornea.  
(New) In the creation of corneal pockets for placement/insertion of a corneal inlay device; and for creation of corneal tunnels for the placement of corneal rings. | lamellar resection of the cornea. | □ In lamellar IEK and corneal harvesting  
□ In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea  
□ In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty  
□ In the creation of a penetrating cut/incision for penetrating keratoplasty and for corneal harvesting.  
□ In patients undergoing ophthalmic surgery or other treatment requiring arcuate cuts/incisions in the cornea.  
□ In patients undergoing ophthalmic surgery or other treatment requiring pocket cuts/incisions in the cornea. |  
□ In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty.  
□ In the creation of a penetrating cut/incision for penetrating keratoplasty and for corneal harvesting.  
□ In patients undergoing ophthalmic surgery or other treatment requiring arcuate cuts/incisions in the cornea.  
□ In patients undergoing ophthalmic surgery or other treatment requiring pocket cuts/incisions in the cornea. |

Operating Principle  
Femtosecond laser photodisruption  
Femtosecond laser photodisruption  
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Femtosecond laser photodisruption
<table>
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<th>ADDITIONAL Predicate</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Mechanism of Action</td>
<td>Cutting and resection surfaces are created by scanned patterns of femtosecond laser micro-photodisruptions in tissue</td>
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</tr>
<tr>
<td>Laser Wavelength</td>
<td>1030 nm</td>
<td>1030 nm</td>
<td>1053 nm</td>
</tr>
<tr>
<td>Maximum Pulse Energy</td>
<td>15 µJ for cataract 2.6 µJ for corneal flaps, pockets and tunnels</td>
<td>15 µJ for cataract 2.6 µJ for corneal flaps for LASIK</td>
<td>2.5 µJ</td>
</tr>
<tr>
<td>Accessory Design</td>
<td>Cone with curved contact lens with integrated suction ring</td>
<td>Cone with curved contact lens with integrated suction ring</td>
<td>Cone with flat contact lens and separate suction ring</td>
</tr>
</tbody>
</table>
VII. 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 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 the depths and geometry of the proposed new corneal pocket treatment patterns using the modified LenSx Laser.
• Evaluation of the accuracy and reproducibility of the depths and geometry of the proposed new corneal tunnel treatment patterns using the modified LenSx Laser.

The LenSx Laser system underwent medical electrical equipment testing and was found in compliance with the following application safety standards:

• ANSI AAMI ES 60601-1 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
• IEC 60601-1-2 – Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility
• IEC 60601-2-22 – Medical Electrical Equipment - Part 2-22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment
• IEC 60825-1 – Safety of Laser Products – Part 1: Equipment Classification and Requirements
• IEC 62304 – Medical Device Software – Software Life Cycle Processes
• IEC 62366 – Medical Devices - Application of Usability Engineering to Medical Devices

Verification and validation of the software updates were conducted in accordance with FDA’s “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,” dated May 11, 2005, and demonstrated that the functional and safety critical requirements are fulfilled.
VIII. Software Verification and Validation

Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device is considered as a “major” level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

IX. Conclusions

The subject of this 510(k) Premarket Notification is to seek clearance for additional new indications for the creation of corneal tunnels and corneal pockets. The LenSx Laser System is essentially the same device as the predicate LenSx Laser System. All modifications were tested to show substantial equivalence to the predicate device as safe and as effective as the predicate device.