April 28, 2025

Alcon Laboratories, Inc.
Tammy Vu
Regulatory Affairs Associate Director
6201 South Freeway
Fort Worth, Texas 76134-2099

Re: K243896
Trade/Device Name: LenSx Laser System (8065998162)
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE, HQC, HNO
Dated: March 21, 2025
Received: March 24, 2025

Dear Tammy Vu:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CLAUDINE H. KRAWCZYK -S

Claudine Krawczyk
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243896

Device Name

LenSx Laser System (8065998162)

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 corneal cuts/incisions (single-plane, multi-plane, and arcuate) during Implantable Collamer Lens (ICL) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid 0MB number."

In accordance with 21 CFR 807.92, Alcon hereby provides the 510(k) summary for the LenSx Laser system.

1. SUBMITTER [per 807.92(a)(1)]

Applicant	Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX 76134-2099
Primary Correspondent	Tammy Vu Associate Director, Regulatory Affairs Alcon Research LLC, on behalf of Alcon Laboratories, Inc. 20511 Lake Forest Drive Lake Forest, CA 92630-7741 +1 (949) 505-7519 tammy.vu@alcon.com
Secondary Correspondent	Ophelia Biggs Senior Director, Regulatory Affairs Alcon Research LLC, on behalf of Alcon Laboratories, Inc. 20511 Lake Forest Drive Lake Forest, CA 92630-7741 +1 (949) 505-7557 ophelia.biggs@alcon.com
Date Prepared	April 22, 2025

2. SUBJECT DEVICE [per 807.92(a)(2)]

Device Trade Name	LenSx Laser System (8065998162)
Regulation Number and Name (Product Code in Parentheses)	21 CFR 886.4390, Ophthalmic Laser (OOE)
Associated Product Codes	HNO, HQC
Regulatory Class	II

3. PREDICATE DEVICE [per [807.92(a)(3)]

Predicate Device	LenSx Laser system
510(k) Number	K173660
Regulation Number and Name (Product Code in Parentheses)	21 CFR 886.4390, Ophthalmic Laser (OOE)
Associated Product Codes	HNO, HQC
Regulatory Class	II

4. DEVICE DESCRIPTION

The LenSx Laser system is an ophthalmic surgical laser which uses focused femtosecond laser pulses to create vapor bubbles which disrupts/separates tissue (photodisruption) within the lens capsule, crystalline lens, and the cornea. A computer-guided delivery system places the laser pulses in a pattern to produce an incision/cut.

The laser pulses are delivered through a sterile, disposable applanating lens and suction ring that contacts the cornea and fixes the eye with respect to the laser delivery system.

The interface between the laser and patient is the Patient Interface that connects to the delivery system which is docked to the patient's cornea. Two models of the Patient Interface accessory are offered for use with the LenSx Laser: the LenSx Laser Patient Interface and the LenSx Laser SoftFit Patient Interface. Both models consist of a sterile, disposable applanating lens and suction ring assembly. The LenSx Laser SoftFit Patient Interface also comes with a soft contact lens that is positioned against the external surface of the Patient Interface glass. For cataract procedures, the LenSx Laser SoftFit Patient Interface is used. The LenSx Laser Patient Interface is used for corneal, flap, tunnel, and pocket incisions. Refer to the Instructions for Use supplied with the LenSx Laser Patient Interface for preparation and application.

The LenSx Laser system is for prescription use and should only be operated by a trained physician. The LenSx Laser system is intended to be used within a clinic(s)/hospital(s)/surgical practice network.

5. INDICATIONS FOR USE

Proposed LenSx Laser system Indications 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 corneal cuts/incisions (single-plane, multi-plane, and arcuate) during Implantable Collamer Lens (ICL) 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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE

CHARACTERISTIC	PREDICATE DEVICE LENSX LASER SYSTEM	SUBJECT DEVICE LENSX LASER SYSTEM
Administrative		
510(k)	K173660	K243896
Regulation Number	21 CFR 886.4390	21 CFR 886.4390
Regulatory Class	Class II	Class II
Product Code	OOE; HNO; HQC	OOE; HNO; HQC
Intended Use (Summarized)	Intended for use in cataract surgery and for the creation of corneal flaps, corneal tunnels and corneal pockets.	Same (Intended for creation of corneal cuts/incisions, pockets, tunnels, and flaps, and for anterior capsulotomy and phacofragmentation).
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. • 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.	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 corneal cuts/incisions (single-plane, multi-plane, and arcuate) during Implantable Collamer Lens (ICL) 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.

CHARACTERISTIC	PREDICATE DEVICE LENSX LASER SYSTEM	SUBJECT DEVICE LENSX LASER SYSTEM
System Features		
Operating Principle	Femtosecond laser photodisruption	Same
Mechanism of Action	Cutting and resection surfaces are created by scanned pattern of femtosecond laser micro-photodisruptions in tissue.	Same
Surgical Field Imaging	Video Microscope and Optical Coherence Tomography	Same
Suction Method	Integrated suction device	Same
Laser Mode of Operation	Pulsed	Same
Laser Gain Medium	Kb:KYW	Same
Laser Wavelength	1030 nm	Same
Laser Pulse Duration	600-800 fs	Same
Laser Pulse Repetition Rate	50 kHz for cataract, 150 kHz for corneal flaps, pockets, and tunnels	50 kHz for cataract and ICL, 150 kHz for corneal flaps, pockets, and tunnels
Maximum Pulse Energy	15 µJ for cataract, 2.6 µJ for corneal flaps, pockets, and tunnels	Same
Maximum Average Power	1 W during service 0.750 W for cataract 0.390 W for corneal flaps, pockets, and tunnels	Same
Maximum Surgical Diameter (Clear Aperture)	12.5 mm	Same
Maximum Depth	8000 µm for cataract, 190 µm for corneal flaps, 400 µm for corneal pockets, and corneal tunnels	Same
OCT Optical Source	Superluminescent Diode	Same
Mode of Operation	Spectral Domain	Same
OCT Wavelength	820-880 nm	Same
OCT Maximum Power	3.0 mW	Same
Illumination for Video Microscope (VM)	LED-Light Emitting Diode	Same
VM Illumination Wavelength	500-650 nm	Same
VM Illumination Maximum Power	0.330 mW	Same
Accessories	LenSx Laser Patient Interface LenSx Laser SoftFit Patient Interface	Same
Software Features		
Software Operating Environment **GUI & Instrument Host**	QNX, version 6.3.2	Same

CHARACTERISTIC	PREDICATE DEVICE LENSX LASER SYSTEM	SUBJECT DEVICE LENSX LASER SYSTEM
Software Version	LenSx Laser System version 2.31	LenSx Laser System, version 2.40 Software modifications to include addition of: • An embedded arcuate LaserArc nomogram calculator. • Horizontal, thick cross, and star phacofragmentation lens cut pattern options. • Capsulorhexis (lens) markers to align the toric intraocular lens orientation. • Corneal incision/cut setting for ICL procedure.

7. SUMMARY OF STUDIES

7.1 Non-Clinical Testing

Biocompatibility

The LenSx Laser console is not intended to have patient contact. The materials used for the device console are common and widely used for ophthalmic and similar applications without reported heath concerns. Per ISO 10993-1, no further biocompatibility testing is required.

Sterilization and Shelf Life

The LenSx Laser console is provided non-sterile and is not intended to be sterilized during routine use. The system console is intended for use with sterile patient interface accessories.

Electromagnetic Compatibility (EMC)/ Wireless / Electrical Safety

Alcon assessed the EMC and electrical / mechanical safety of the LenSx Laser system according to IEC 60601-1, IEC 60601-1-2, IEC 60601-2-22, IEC 60601-4-2, and the final FDA guidance document "*Electromagnetic Compatibility (EMC) of Medical Devices*," issued June 6, 2022. The subject device met all requirements from the aforementioned standards and followed FDA recommendations where applicable from said guidance document.

Optical Radiation Safety

Alcon assessed the optical radiation safety of the LenSx Laser System and found that the retinal exposures are in compliance with limits for Group 1 devices defined in ANSI Z80.36-2021.

Software

Software verification and validation testing were conducted for the LenSx Laser system and met all requirements. In addition, documentation was provided as recommended by FDA

guidance for the "*Content of Premarket Submissions for Software Device Software Functions*," issued on June 14, 2023. The software was found to fit in the category of products that would require Enhanced Documentation Level because the failure or latent flaw of the device software function would present a hazardous situation with a probable risk of serious injury to either a patient, user of the device or others in the environment of use prior to the implementation of the risk control measures.

Alcon also fulfilled FDA's cybersecurity recommendations for the subject device in accordance with FDA guidance, "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*," dated September 2023.

Performance Testing

The LenSx Laser system successfully completed bench testing which demonstrates the system's ability to meet all intended design specifications. Features introduced with the subject device have minor technological differences and do not adversely affect the safety and effectiveness of the device. Additional performance regression and toric markings capsular bag pull tests were performed to verify that these features function as intended and meet applicable design requirements. The performance data demonstrated that the device performs as intended.

Bench testing, when coupled with software verification and validation testing presented for the subject device, provides reasonable assurance that the system remains safe and effective for its intended use and furthermore, that it is substantially equivalent to the predicate device, LenSx Laser system.

7.2 Animal/Clinical Testing

The system design, architecture, indications for use, materials, and patient interface accessories are the same for both the subject device and predicate device. Therefore, the risk assessment for the subject device did not require any animal or clinical testing as mitigation against any identified risks.

8 CONCLUSION

The modified LenSx Laser system shares the same intended use as the predicate device. The hardware and software changes between the predicate and the modified device do not raise new questions of safety and efficacy of the new device. The technological characteristics affecting clinical performance are similar to those of the predicate device previously listed. Risk profiles are equivalent between the subject device and the predicate device.

The predicate devices and the subject devices have been developed and manufactured in compliance with 21 CFR 820 and ISO 14971. Non-clinical testing noted above demonstrated that the functional requirements were met, and that the subject device is equivalent to the predicate device. Therefore, the modified LenSx Laser system is deemed substantially equivalent to the currently cleared, LenSx Laser system.