September 24, 2025

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

Re: K252682
Trade/Device Name: LenSx Laser System (8065000944)
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: OOE, HNO, HQC
Dated: August 22, 2025
Received: August 25, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252682

Please provide the device trade name(s).

LenSx Laser System (8065000944)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

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

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 Senior Manager, 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	September 16, 2025

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

Device Trade Name	LenSx Laser System (8065000944)
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 (8065998162)
510(k) Number	K243896
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

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.

6. TECHNOLOGICAL COMPARISON

The technological characteristics are the same to those of the predicate device previously cleared in K243896.

CHARACTERISTIC	PREDICATE DEVICE LENSX LASER SYSTEM	SUBJECT DEVICE LENSX LASER SYSTEM
Administrative		
510(k)	K243896	K252682
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 creation of corneal cuts/incisions, pockets, tunnels, and flaps, and for anterior capsulotomy and phacofragmentation.	Same
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 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.	Same

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 and ICL, 150 kHz for corneal flaps, pockets, and tunnels	Same
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
Software Version	LenSx Laser System version 2.40	Same

7 NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY

The risk assessment for the subject device did not require any non-clinical or clinical testing as mitigation against any identified risks. Non-clinical testing previously performed in the predicate device are deemed applicable to the subject device and can be referenced in K243896.

8 CONCLUSION

The modified LenSx Laser system shares the same intended use, indications for use, technological characteristics, and risk profiles as the predicate device. Non-clinical testing previously performed and cleared in K243896 are deemed applicable to the subject device. The predicate device and the subject device have been developed and manufactured in compliance with 21 CFR 820 and ISO 14971. Therefore, the modified LenSx Laser system is deemed substantially equivalent to the currently cleared, LenSx Laser system.