January 10, 2024

Alcon Laboratories, Inc.
Rita De Rama
Manager, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134

Re: K233902
Trade/Device Name: Centurion™ Vision System (Active Sentry™) (8065753057)
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: December 6, 2023
Received: December 11, 2023

Dear Rita De Rama:

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.

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: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233902

Device Name

Centurion™ Vision System (Active Sentry™) (8065753057)

Indications for Use *(Describe)*

The Centurion™ Vision System (Active Sentry™) is indicated for emulsification, separation, irrigation, and aspiration of cataracts, residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intraocular lens injection.
The AutoSert™ IOL Injector Handpiece is intended to deliver qualified AcrySof™ intraocular lenses into the eye following cataract removal.
The AutoSert™ IOL Injector Handpiece achieves the functionality of injection of intraocular lenses.
The AutoSert™ IOL Injector Handpiece is indicated for use with AcrySof ™ lenses SN60WF, SN6AD1, SN6AT3 through SN6AT9, as well as approved AcrySof ™ lenses that are specifically indicated for use with this inserter, as indicated in the approved labeling of those lenses.

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.

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510(k) Summary

Prepared on: 2024-01-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Alcon Laboratories, Inc.
Applicant Address	6201 South Freeway Fort Worth TX 76134 United States
Applicant Contact Telephone	949 886 5787
Applicant Contact	Mrs. Rita De Rama
Applicant Contact Email	rita.derama@alcon.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Centurion™ Vision System (Active Sentry™) (8065753057)
Common Name	Phacofragmentation system
Classification Name	Unit, Phacofragmentation
Regulation Number	886.4670
Product Code	HQC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K161794	CENTURION™ Vision System (Active Sentry™)	HQC

Device Description Summary

21 CFR 807.92(a)(4)

Alcon's CENTURION™ Vision System is an ophthalmic surgical instrument designed to provide cataract extraction using the CENTURION™ OZil™handpiece, the CENTURION™ Active Sentry™ handpiece, and the INFINITI™ OZil™ handpiece.
The CENTURION™ Vision System is intended for use in small incision cataract lens extraction and IOL injection surgical procedures. This system allows the surgeon to emulsify and aspirate the lens in the eye, while replacing aspirated fluid and lens material with balanced salt solution (BSS™). This process maintains a stable (inflated) eye chamber volume. Using system controls, the surgeon regulates the amount of power applied to the handpiece tip, the rate of aspiration,vacuum, and the flow of BSS™ irrigating solution. The system includes a footswitch to enable the surgeon to control flow of fluidics, aspiration rate, phacoemusification (phaco) power, vitrectomy cut rate, IOL injection rate, and coagulation power.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Centurion™ Vision System (Active Sentry™) is indicated for emulsification, separation, irrigation, and aspiration of cataracts, residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intraocular lens injection.
The AutoSert™ IOL Injector Handpiece is intended to deliver qualified AcrySof™ intraocular lenses into the eye following cataract removal.
The AutoSert™ IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The AutoSert™ IOL Injector Handpiece is indicated for use with AcrySof ™ lenses SN60WF, SN6AD1, SN6AT3 through SN6AT9, as well as approved AcrySof ™ lenses that are specifically indicated for use with this inserter, as indicated in the approved labeling of those lenses.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same between the subject device and the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

A modification to add a new Warning statement in the labeling for the TurboSonics™ ultrasonic tips, which are accessories for the CENTURION® Vision System, is the only change being made to the predicate device.
The modified CENTURION™ Vision System (Active Sentry™) is substantially equivalent to the originally submitted CENTURION™ Vision System (Active Sentry™) in that both devices:
• Have the same indication for use.
• Use the same operating principle.
• Use the same technology, including components used.
• Are of the same design, incorporate the same materials, have the same shelf life, and are packaged and sterilized using the same materials and processes.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical testing was previously performed in the predicate device and can be referenced in K161794.
A modification to add a new Warning statement in the labeling for the TurboSonics™ ultrasonic tips, which are accessories for the CENTURION® Vision System, is the only change being made to the predicate device. Thus, the change made to the subject device described in this submission is substantially equivalent to the predicate device.