December 4, 2024

Alcon Laboratories, Inc.
Ganesh Balachandar
Regulatory Affairs Manager
6201 South Freeway
Fort Worth, Texas 76134

Re: K242184
Trade/Device Name: Alcon 27GA Chandelier; Alcon 27+ DS Wide Angle Endoilluminator; Alcon 27+ DS Endoilluminator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: MPA
Dated: October 25, 2024
Received: October 25, 2024

Dear Ganesh Balachandar:

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

510(k) Number *(if known)*
K242184

Device Name
- Alcon 27GA Chandelier
- Alcon 27+ DS Wide Angle Endoilluminator
- Alcon 27+ DS Endoilluminator

Indications for Use *(Describe)*

Alcon 27GA Chandelier

The 27GA Chandelier is indicated for use during posterior segment ophthalmic surgery.

Alcon 27+ DS Wide Angle Endoilluminator

The 27+DS Wide-Angle Endoilluminator is indicated for use during posterior segment ophthalmic surgery.

Alcon 27+ DS Endoilluminator

The 27 + DS Endoilluminator is indicated for use during posterior segment ophthalmic surgery.

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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"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 OMB number."

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

1. SUBMITTER

Applicant	Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX 76134-2099
Primary Correspondent	Ganesh Balachandar Regulatory Affairs Manager Alcon Research LLC, on behalf of Alcon Laboratories, Inc. 20511 Lake Forest Drive Lake Forest, CA 92630-7741 +1 (949) 322-5101 ganesh.balachandar@alcon.com
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Date Prepared	December 4, 2024

2. SUBJECT DEVICES

Device Trade Name	• Alcon 27GA Chandelier • Alcon 27+ DS Wide Angle Endoilluminator • Alcon 27+ DS Endoilluminator
Classification Number and Name (Product Code in Parentheses)	• 21 CFR 876.1500 Endoscope and accessories (MPA)
Regulatory Class	II

3. PREDICATE DEVICES

For Alcon 27GA Chandelier:	
Predicate Device	25GA Chandelier
510(k) Number	K875005
Classification Number and Name (Product Code in Parentheses)	21 CFR 876.1500 Endoscope and accessories (MPA)
Regulatory Class	II

For Alcon 27+ DS Wide Angle Endoilluminator:	
Predicate Device	25GA Wide Angle Endoilluminator
510(k) Number	K875005
Classification Number and Name (Product Code in Parentheses)	21 CFR 876.1500 Endoscope and accessories (MPA)
Regulatory Class	II

For Alcon 27+ DS Endoilluminator:	
Predicate Device	27+ Straight Endoilluminator
510(k) Number	K110951
Classification Number and Name (Product Code in	21 CFR 876.1500 Endoscope and accessories (MPA)

Parentheses)	
Regulatory Class	II

4. DEVICE DESCRIPTION

As part of this premarket notification Alcon presents three new endoilluminators, compatible with the UNITY VCS device cleared in K233876 (clearance date: June 21, 2024). The table below lists the endoilluminators covered within scope of this premarket notification.

Device Name	Catalog Number	Device Classification	Product Code	CFR Number
Alcon 27 GA Chandelier	8065000252	Class II	MPA	21 CFR 876.1500, Endoscope and accessories
Alcon 27+ DS Wide Angle Endoilluminator	8065000253			
Alcon 27+ DS Endoilluminator	8065000256			

Alcon 27GA Chandelier

The Alcon 27GA Chandelier provides a hands-free wide field of illumination for vitreoretinal procedures. The distal end of the device incorporates a short, tapered fiber optic to provide wide angle illumination projected from a pars plana position of the eye. The distal end consists of a tapered fiber, which is inserted into the eye through the Alcon 27GA entry system. The fiber is malleable so the physician can shape it to form a stable service loop, position the tip, and minimize interference with the lid speculum.

Alcon 27+ DS Wide Angle Endoilluminator

The Alcon 27+ DS WA Endoilluminator offers wide-angle illumination, featuring a sapphire lens at the distal end of the probe. This design ensures consistent, low-glare illumination across a broad field of view. Additionally, it incorporates a Dynamic Stiffener (DS) element—a retractable stiffener designed to minimize needle deflection at the proximal end of the stainless steel cannula, as opposed to the fixed stiffener used in previous models.

Alcon 27+ DS Endoilluminator

The Alcon 27+ DS Endoilluminator transmits light energy into the eye and incorporates a DS element at the proximal end of the stainless-steel cannula.

5. INDICATIONS FOR USE

Alcon 27GA Chandelier

The 27GA Chandelier is indicated for use during posterior segment ophthalmic surgery.

Alcon 27+ DS Wide Angle Endoilluminator

The 27+DS Wide-Angle Endoilluminator is indicated for use during posterior segment ophthalmic surgery.

Alcon 27+ DS Endoilluminator

The 27 + DS Endoilluminator is indicated for use during posterior segment ophthalmic surgery.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE

Tables 1 to 3 below compare the intended use and technological characteristics of each Alcon 27GA Endoilluminator with their respective predicate devices. These tables illustrate how the subject endoilluminators are substantially equivalent with the predicate devices, as the subtle differences in technological attributes do not raise concerns of safety of effectiveness.

Table 1: SE Table 25GA Chandelier (K875005) and 27GA Chandelier (K242184)

Attributes	25 GA Chandelier (Predicate device, K875005)	27 GA Chandelier (Subject device, K242184)
Intended Use	Endoscope and accessories	Same
Energy sources	Light	Same
Patient contact material (Direct or fluid path)	PMMA, Polyimide, Adhesive (Cyanoacrylate)	PMMA, ABS, Adhesive (Cyanoacrylate)

Attributes	25 GA Chandelier (Predicate device, K875005)	27 GA Chandelier (Subject device, K242184)
Length (Fiber optic)	0.26”	Same
(Device only) Tip Outer Diameter	(Fiber and End of Hub) 25 Ga – 0.014”	(Fiber and End of Hub) 27 Ga - 0.010"
Light Transmission (Universal Flux Ratio)	0.150 UFR	0.096 UFR
Connector	RFID, ACMI	Same
Method of sterilization	Ethylene Oxide	Same

Attributes	25 GA Chandelier (Predicate device, K875005)	27 GA Chandelier (Subject device, K242184)
Packaging configuration	Needle cover: Polypropylene Lid: Tyvek Soft tray: Thermoforming film	Same
Shelf life	2 years	Same

Table 2: SE Table 25+ Wide Angle (K875005) and 27+ DS Wide Angle (K242184)

Attributes	25+ Wide Angle (Predicate Device, K875005)	27+ DS Wide Angle (Subject device, K242184)
Intended Use	Endoscope and accessories	Same
Energy sources	Light	Same
Patient contact material (Direct or fluid path)	Stainless steel, Sapphire	Stainless steel, MP35N, Sapphire
Length (Device only)	3.9" (Shell and Needle)	Same
Tip Outer Diameter	25 Ga – 0.020”	27 Ga - 0.016"
Light Transmission (Universal Flux Ratio)	0.060 UFR	0.047 UFR

Attributes	25+ Wide Angle (Predicate Device, K875005)	27+ DS Wide Angle (Subject device, K242184)
Connector	RFID, ACMI	Same
Method of sterilization	Ethylene Oxide	Same
Packaging configuration	Needle cover: Polypropylene Lid: Tyvek Soft tray: Thermoforming film	Same
Shelf life	3 years	2 years

Table 3: SE Table 27+ Endoilluminator (K110951) and 27+ DS Endoilluminator (K242184)

Attributes	27+ Endoilluminator (Predicate Device, K110951)	27+ DS Endoilluminator (Subject device, K242184)
Intended Use	Endoscope and accessories	Same
Energy sources	Light	Same
Patient contact material (Direct or fluid path)	Stainless steel, PMMA, Teflon, Adhesive (Cyanoacrylate)	Stainless steel, PMMA
Length (Device only)	3.9"(Shell and Needle)	Same

Attributes	27+ Endoilluminator (Predicate Device, K110951)	27+ DS Endoilluminator (Subject device, K242184)
Tip Outer Diameter	27 Ga - 0.016"	Same
Light Transmission (Universal Flux Ratio)	0.075 UFR	Same
Connector	RFID, ACMI	Same
Method of sterilization	Ethylene Oxide	Same
Shelf life	2 years	Same

7. SUMMARY OF STUDIES

7.1 Non-Clinical Testing

Biocompatibility

Alcon conducted biocompatibility testing on the patient-contacting devices and met ISO 10993, Biocompatibility of medical devices requirements for chemical characterization, cytotoxicity, sensitization, irritation, and acute systemic toxicity. Packaging materials passed cytotoxicity requirements from ISO 11607-1, Packaging for terminally sterilized medical devices and ASTM F2475, Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials.

Sterilization and Shelf Life

Alcon performed sterilization testing on the subject devices. Tested devices passed the predetermined acceptance criteria in accordance with ISO 11135, Sterilization of health-care products — Ethylene oxide and ISO 10993-7, Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals. The subject devices were sterilized by ethylene oxide (EO). The subject devices have been shown to be sterilizable to a sterility assurance level (SAL) of 10^{-6}, and the sterilization process has been validated per the required standard.

The subject devices utilize the same packaging configuration as their predicates, undergoing ethylene oxide (EO) sterilization and pre-conditioning in accordance with ASTM D4169, Standard Practice for Performance Testing of Shipping Containers and Systems. Additionally, accelerated aging was performed in compliance with ASTM F1980, the Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices. All tested units successfully met the predetermined acceptance criteria for package integrity, which included visual inspection, seal strength, and bubble leak tests, in accordance with ISO 11607-1, Packaging for Terminally Sterilized Medical Devices.

Performance Testing

Safety tests demonstrated the compliance of the subject devices to the appropriate standards. Biocompatibility evaluations of materials coming into contact with the patient or patient fluid path demonstrated compliance with the appropriate standard from the ISO 10993 series.

Technological characteristics affecting clinical performance are similar to those of the predicate devices previously listed. Like the predicate devices, the subject devices have been developed and manufactured in compliance with the following standards:

- ISO 14971, Medical devices — Application of risk management to medical devices
- ISO 15004-1, Ophthalmic instruments - Fundamental requirements and test methods, Part 1: General requirements applicable to all ophthalmic instruments
- ISO 15752, Ophthalmic Instruments - Endoilluminators - Fundamental Requirements and Test Methods for Optical Radiation Safety

- ANSI Z80.36, Ophthalmics - Light Hazard Protection for Ophthalmic Instruments

Light Hazard Testing:

The three subject devices were evaluated for luminous flux, aphakic irradiance and thermal irradiance for the purposes of comparison with the predicate devices and compliance to ANSI Z80.36, Ophthalmics - Light Hazard Protection for Ophthalmic Instruments and ISO 15752, Ophthalmic Instruments - Endoilluminators - Fundamental Requirements and Test Methods for Optical Radiation Safety.

The subject devices have a similar luminous flux and meet aphakic and thermal safety standards comparable to the predicate devices.

Non-clinical testing noted above has demonstrated that the functional requirements have been met and that the subject devices are equivalent to the predicate devices.

7.2 Animal/Clinical Testing

The risk assessment for the subject devices did not require any animal or clinical testing as mitigation against any identified risks.

8. CONCLUSION

The subject devices share the same intended use as the predicate devices. Their indications for use are equivalent with each other. The technological characteristics affecting clinical performance are similar to those of the predicate devices previously listed. Risk profiles are equivalent between the subject devices and the predicate devices. 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 devices are equivalent to the predicate devices.

Therefore, the subject devices, the Alcon 27GA Chandelier, Alcon 27+ DS Wide Angle Endoilluminator, and Alcon 27+ DS Endoilluminator, are deemed substantially equivalent to their predicate devices, the 25GA Chandelier, 25GA Wide Angle Endoilluminator and 27+ Straight Endoilluminator, respectively.