August 23, 2021

Alcon Laboratories, Inc.
Jwalitha Shankardas
Associate Director, Global Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134

Re: K212039
Trade/Device Name: CLAREON MONARCH IV IOL Delivery System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I, reserved
Product Code: MSS
Dated: June 29, 2021
Received: June 30, 2021

Dear Jwalitha Shankardas:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

For Bennett Walker, Ph.D.
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K212039

Device Name

CLAREON MONARCH IV IOL Delivery System

Indications for Use *(Describe)*

The CLAREON MONARCH IV IOL Delivery System is for implantation of qualified Alcon foldable IOLs. No unqualified lenses should be used with the CLAREON MONARCH IV IOL Delivery System.

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 21 CFR section 807.92.

I. SUBMITTER

Company:	Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX 76134-2099, USA
Primary Contact Person:	Jwalitha Shankardas, Global Regulatory Affairs
Phone:	817-551-8582
Email:	Jwalitha.shankardas@alcon.com

Date Prepared:	June 28, 2021

II. DEVICE

Trade Names:	CLAREON MONARCH IV IOL Delivery System
Common Name:	Folders and Injectors, Intraocular lens (IOL)
Classification Name:	Folders and Injectors, Intraocular lens (IOL)
Device Classification:	Class I- 21CFR 886.4300
Product Code:	MSS

III. PREDICATE DEVICE

Trade Names:	Monarch III IOL Delivery System, Monarch III C cartridge, Monarch III Handpiece (H4)
510K Number	K112977
FDA Clearance date	03/27/2012
Submitter	Alcon Laboratories, Inc.
Common Name:	Folders and Injectors, Intraocular lens (IOL)
Classification Name:	Folders and Injectors, Intraocular lens (IOL)

Device Classification:	Class I- 21CFR 886.4300
FDA Panel	Ophthalmic
Product Code:	MSS

IV. DEVICE DESCRIPTION

The CLAREON MONARCH IV IOL Delivery System consists of two parts. An autoclavable, reusable, titanium handpiece and a sterile, single-use cartridge are used for implanting foldable intraocular lenses into the eye following removal of the natural crystalline lens.

The system provides a controlled means to reliably place Alcon qualified intraocular lenses (IOLs) into the capsular bag when a qualified combination of handpiece, cartridge, Alcon foldable IOL, and ophthalmic viscosurgical device (OVD) is used.

The cartridge is loaded by inserting the IOL into the opening in the back of cartridge after OVD is applied to the inner lumen of the cartridge. The loaded cartridge is installed into the handpiece and the IOL is delivered through the cartridge nozzle.

V. INDICATIONS FOR USE

The CLAREON MONARCH IV IOL Delivery System is for implantation of qualified Alcon foldable IOLs. No unqualified lenses should be used with the CLAREON MONARCH IV IOL Delivery System.

VI. INDICATIONS FOR USE COMPARISON

The indications for use of the CLAREON MONARCH IV IOL Delivery System are the same as the predicate device.

VII. TECHNOLOGICAL COMPARISON

The technological characteristics of the CLAREON MONARCH IV IOL Delivery System are equivalent to those of the predicate device, MONARCH III IOL Delivery System in terms of operating principle, technological characteristics, component materials, manufacturing process, biocompatibility, cleaning, steam sterilization method, performance, and FDA-recognized standards used for performance testing. The CLAREON MONARCH IV IOL Delivery System

has the same intended use, and is compatible with the same Alcon's Monarch cartridges as its predicate.

The CLAREON MONARCH IV IOL Delivery System is primarily differentiated from its predicate by minor design change optimizations to the handpiece housing, knob and plunger for the Clareon IOL design.

VIII. NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS

The following performance data were provided in support of the substantial equivalence determination.

- Compatibility and delivery performance with qualified Monarch cartridges, Clareon IOLs and OVDs in accordance with ISO 11979-3-12.
- Biocompatibility of the patient-contact aspects of the CLAREON MONARCH IV IOL Delivery System in accordance with the intended use of the device (in accordance with ISO 10993-18-20 and ISO 10993-5-09).
- Reprocessing and sterilization over the claimed use life in accordance with ISO 17664-17, ISO 17665-1-06 and ISO 14937-09.
- Human factors and usability for safe and effective use by intended users in accordance with IEC 62366-1-20 as well as the FDA guidance, *Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff; 2016.*

The technological characteristics that determine the functionality and performance of the CLAREON MONARCH IV IOL Delivery System is substantially equivalent to the predicate device. The data from the non-clinical tests demonstrate that the safety and effectiveness profile of the CLAREON MONARCH IV IOL Delivery System is equivalent to that of the legally marketed predicate device.