November 1, 2019

Alcon Research, LLC
Nickerson Hill
Associate Director, Global Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134

Re: K191650
Trade/Device Name: LEGION System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: September 26, 2019
Received: September 27, 2019

Dear Nickerson Hill:

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 Tieuvi Nguyen, PhD
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191650

Device Name
LEGION System

Indications for Use *(Describe)*

The Legion™ System 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 intra-ocular 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.

5 510(k) Summary K191650

This summary document has been prepared in accordance with 21 CFR 807.92.

I. Submitter of the 510(k)

Company:	Alcon Research, Ltd. (on behalf of Alcon Laboratories, Inc) 6201 South Freeway Fort Worth, TX 76134-2099, USA
Primary Contact Person:	Nickerson Hill, Associate Director, Global Regulatory Affairs
Phone:	817-302-5700
Email:	Nickerson.hill@alcon.com
Date Prepared:	June 19, 2019

II. Devices Subject to this 510(k)

Trade Name:	LEGION™ System
Common Name:	Phacofragmentation Unit
Classification Name:	Phacofragmentation Unit
Device Classification:	Class II – 21 CFR 886.4670
FDA Panel:	Ophthalmic
Product Code:	HQC

III. Predicate Device

Trade Name:	CENTURION™ Vision System (Active Sentry™)
510(k) Number:	K161794
FDA Clearance Date:	April 14, 2017
Submitter:	Alcon Research, Ltd.
Common Name:	Phacofragmentation Unit
Classification Name:	Phacofragmentation Unit
Device Classification:	Class II – 21 CFR 886.4670
FDA Panel:	Ophthalmic
Product Code:	HQC

IV. Device Description

The LEGION™ System is intended for use in anterior segment ophthalmic surgery procedures that require simultaneous lens extraction via phacoemulsification, irrigation and aspiration, and associated procedures such as anterior vitrectomy, coagulation and intraocular lens (IOL) insertion.

The LEGION™ System consists of a standalone tabletop console, which performs the core functionalities for cataract lens extraction. The LEGION™ System's console provides two electrical connector ports that support the CENTURION™ series of ultrasound handpieces, an electric vitrectomy cutter, the Alcon AutoSert™ IOL Injector and a Coagulation accessory port on both sides of the Fluidics module. The OZIL torsional technology of Alcon's phacoemulsification handpieces and tips operates with ultrasonic torsional oscillations which can be used exclusively, combined or alternated with traditional longitudinal phacoemulsification. The traditional modalities of ultrasonic power control including continuous, pulsed, and burst application of ultrasonic power, as well as duty cycle management are available.

The same fluidics module and overall fluid management system (FMS) design of the predicate device (CENTURION™ Vision System) is used on the LEGION™ System. The FMS is an interface between the LEGION™ System Console (Fluidics Module) and the surgical handpieces, used to regulate irrigating fluid to the handpiece, aspirate fluid and debris from the handpiece, monitor irrigation and aspiration pressure and deposit the fluid and debris in a sealed drainage bag . This single assembly contains a rigid plastic fluidic chamber, non-invasive pressure/vacuum sensor, drain bag, irrigating fluid administration line, as well as irrigation and aspiration handpiece tubing.

Two types of FMS can be used with the LEGION™ System: Single Use and MultiPak FMS. The MultiPak FMS is intended to be a day-use cassette for up to 12 consecutive procedures (patients). The primary difference between the single use and MultiPak FMS is the ability to replace the single use sterile irrigation/aspiration (I/A) manifold and drain bag. Several design aspects have been implemented to reduce the risk of cross-contamination when using the MultiPak FMS.

The LEGION™ System utilizes gravity-based irrigation (i.e. irrigation pressure derived from the height of the irrigation fluid bag or bottle). The LEGION™ System can be used in conjunction with a manual IV pole, or can be used with the optional LEGION™ cart, which is equipped with a powered IV pole.

The LEGION™ System supports anterior vitrectomy procedures via compatibility with the reusable LEGION™ anterior vitrectomy handpiece and consumable vitrectomy probe. The reusable anterior vitrectomy handpiece drives the guillotine-style consumable vitrectomy probe to achieve anterior vitrectomy functionality.

The LEGION™ System provides bipolar coagulation capability via support for Alcon coagulation handpieces and tips, with a power rating identical to the predicate device.

V. Indications for Use

The LEGION™ System 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 intra-ocular 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.

VI. Comparison to Technological Characteristics of the Predicate Device

The technological characteristics of the LEGION™ System are equivalent to those of the predicate device. The LEGION™ System has the same intended use as its predicate, and is compatible with the same Alcon phacoemulsification and Irrigation/Aspiration (I/A) tips and handpieces. The LEGION™ System also supports anterior vitrectomy procedures via the LEGION™ vitrectomy handpiece and probe, which achieves this action via a guillotine-style cutter. The LEGION™ System also uses the same Fluid Management System (FMS) technology as its predicate.

The LEGION™ System is primarily differentiated from its predicate by its smaller size, and by the removal of some features. Additionally, the LEGION™ System is compatible with an FMS MultiPak, designed to support use over multiple surgeries in a single day.

VII. Performance Data

Data and information on the LEGION™ System in the present 510(k) submission demonstrate:

- Compatibility with Alcon phacoemulsification handpieces and tips
- Ultrasound frequency (longitudinal and torsional) consistent with the predicate device
- Compatibility with Alcon I/A handpieces and tips
- Peristaltic aspiration in accordance with design requirements
- Vacuum range in accordance with design requirements
- Accuracy of:
    - Aspiration rate
    - Pressure sensing (irrigation and aspiration)
    - Vacuum control
- Occlusion Break Surge performance
- Verification of effectiveness of design aspects preventing cross-contamination during use of the FMS MultiPak
- Anterior vitrectomy probe cut rate and quality
- Coagulation power rating
- Compatibility with Alcon IOL injection handpiece

- Biocompatibility of the patient-contact aspects of the LEGION System proposed herein in accordance with the intended use of the devices
- Sterility and performance of the Anterior Vitrectomy Kit and FMS Paks over the claimed shelf life
- Electromagnetic compatibility and electrical safety of the LEGION System in accordance with FDA-recognized standards

VIII. Conclusions

Data and information summarized herein demonstrate substantial equivalence of the LEGION™ System to the claimed predicate device.