DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 14, 2017

Alcon Research, Ltd.
Mr. Paul Swift, RAC
Director, Global Regulatory Affairs Project
6201 South Freeway Dr.
Fort Worth, TX 76134-2099

Re: K161794
Trade/Device Name: Centurion Vision System (Active Sentry®)
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: March 6, 2017
Received: March 8, 2017

Dear Mr. Swift:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Bradley S. Cunningham -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161794

Device Name
CENTURION VISION SYSTEM (Active Sentry™)

Indications for Use *(Describe)*
The CENTURION® Vision system (Active SentryTM) 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 the ACRYSOF lenses SN6OWF, SNWAD1, 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

5 510(k) Summary

This 510(k) summary document has been prepared in accordance with section 21 CFR 807.92.

Submitter of the 510(k)

Company:	Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX 76134-2099, USA
Primary Contact Person:	Paul Swift, RAC Director, Global Regulatory Affairs
Phone:	817.615.2952
Fax:	817.551.4630
Email:	Paul.Swift@alcon.com

Date Prepared:	December 16, 2016

Devices Subject to this 510(k)

Trade Names:	CENTURION® Vision System (Active Sentry®)
Regulation Number:	21 CFR 886.4670
Regulation Name:	Phacofragmentation System
Regulatory Class:	Class II
Product Code:	HQC

A. Predicate Device

CENTURION Vision System
K121555
December 21, 2012

B. Device Description

Alcon's CENTURION ® Vision System is an ophthalmic surgical instrument designed for use in 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. 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, phaco power, vitrectomy cut rate, IOL injection rate, and coagulation power.

C. Indications for Use

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 the ACRYSOF lenses SN6OWF, SNWAD1, 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.

D. Comparison to Technological Characteristics with the Predicate Device

Table 1 Substantial equivalence comparison

Characteristic	CENTURION® Vision System	CENTURION® Vision System (Active Sentry®)
510 (k) #	K121555	K161794
Intended Use	Anterior Segment Ophthalmic Surgery	Anterior Segment Ophthalmic Surgery
Hardware (Modular) Design	Yes	Yes
Microprocessor based	Yes	Yes
Programmable for multiple surgeons	Yes	Yes
User Interface	Footswitch, Touch Screen and Remote control	Footswitch, Touch Screen and Remote control
Self-Diagnostics	Yes	Yes
Real-Time Display	Yes	Yes
Software platform	Windows based	Windows based
U/S Pulse Mode	Yes	Yes
Heads-Up Display	Yes (optional only)	Yes (optional only)
Anterior Vitrectomy	Yes	Yes
Posterior Vitrectomy	No	No
Occlusion Mode		
Longitudinal	Yes	Yes
Torsional	Yes	Yes
Operating U/S Frequency		
Longitudinal	44kHz nominal	44kHz nominal
Torsional	32kHz nominal	32kHz nominal
Support for ALCON® UltraChopper® Tip	Yes (K091777)	Yes (K091777)
Power Watch Mode	Yes	Yes
IOL Injection Mode	Yes	Yes
Coagulation/Cautery/Diathermy	Yes	Yes
Irrigation		
Gravity	Yes	Yes
Pressurized	Yes	Yes
Maximum Irrigation Pressure Threshold (in mmHg)	Less than 207	Less than 207
Aspiration Pump Type	Peristaltic	Peristaltic
Vacuum Range (in mmHg)	0-650(+)	0-650(+)
Console Screen	Active Matrix color LCD	Active Matrix color LCD
Multi-function Foot Pedal		
Wired	Yes	Yes
Wireless	Yes	Yes

Characteristic	CENTURION® Vision System	CENTURION® Vision System (Active Sentry®)
Remote Control	Yes(if selected)	Yes(if selected)
Automatic IV Pole	Yes	Yes
Voice Confirmation	Yes	Yes
Prime Mode	Yes	Yes
Machine Height Width and Depth	63” x 23” x 30” max	63” x 23” x 30” max
Machine Weight	235 lbs max	235 lbs max
Electrical Power Specifications	100-240 V AC, 50/60 Hz	100-240 V AC, 50/60 Hz
Operating Temperature Range	10 – 35°C	10 – 35°C
Maximum Humidity (RH = Relative Humidity)	95% RH noncondensing	95% RH noncondensing
Disposable Pack - Provided Sterile	Yes	Yes
Disposable Pack - Method of sterilization	EtO and Gamma	EtO and Gamma

E. Performance Data

Performance of the CENTURION® Vision System (Active Sentry®) has been demonstrated through various performance validations, biocompatibility testing and electromagnetic compatibility and electrical safety testing.

Table 2: Summary of biocompatibility studies for the Active Sentry® Handpiece

Biocompatibility Testing for Active Sentry Handpiece	Cell Line/ Species	Test Media Extract	Test Result
Cytotoxicity ISO Elution Method 1X MEM	L-929 Mouse	MEM Extract	**PASS**
Cytotoxicity ISO MTT Method	L-929 Mouse	MEM Extract	**PASS**
Sensitization ISO Maximization Sensitization Study	Guinea Pig	Saline & Sesame Oil Extracts	**PASS**
Acute Systemic Toxicity ISO Acute Systemic Toxicity Study	Mouse	Saline & Sesame Oil Extracts	**PASS**
Ocular Irritation ISO (Intraocular Injection) Method	Rabbit	Balanced Salt Solution (BSS® Irrigating Solution)	**PASS**
Material Characterization (Leachables) ISO Method	Not Applicable	Isopropanol and Purified Water	**PASS**

Table 3: CENTURION® Vision System (Active Sentry®) electromagnetic compatibility and electrical safety

Document Number	Revision	Document Name	Result
EN 60601-1	2013	Medical Electrical Equipment, Part 1 – General requirements for basic safety and essential performance. (Including A1:2013) *(Equivalent to IEC 60601-1: 2005+ A1: 2012)*	PASS
EN 60601-1-2	2007	Medical electrical equipment Part 1: General requirements for basic safety and essential performance – 2. Collateral Standard: Electromagnetic compatibility–Requirements and test. *(Equivalent to IEC 60601-1-2: 2007)*	PASS
EN 60601-2-2	2009	Medical electrical equipment – Part 2: General requirements for basic safety and essential performance – Particular requirements for the Safety of high frequency surgical equipment. *(Equivalent to IEC 60601-2-2: 2009)*	PASS
EN 60601-1-8	2007	Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance – 6. Collateral standard for alarm systems *(Equivalent to IEC 60601-1-8: 2006)*	PASS
EN 80601-2-58	2009	Medical Electrical Equipment, Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery *(Equivalent to IEC 80601-2-58:2008)*	PASS
IEC 60601-1-6	2010	Medical Electrical Equipment Part 1-6: General requirements for safety – collateral standard: usability (Including A1:2013)	PASS
IEC 62366	2007	Medical Devices – Application of usability engineering to medical devices (Including A1:2014)	PASS

F. Conclusions

The modified CENTURION® Vision System (Active Sentry®) is substantially equivalent to the originally submitted CENTURION® Vision System in that both devices:

- have the same indicated use,
- use the same operating principle,
- incorporate the same basic phaco handpiece, same consumables and accessories cleared in the original submission as a system
- 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;

In summary, the changes made to the CENTURION® Vision System (Active Sentry®) described in this submission are substantially equivalent to the predicate device: CENTURION® Vision System.