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

August 22, 2014

Alcon Research Ltd.
Mr. Robert Lundberg
Vice President Regulatory Affairs, VGR
20511 Lake Forest Drive
Lake Forest, CA 92630

Re: K141065
Trade/Device Name: CONSTELLATION® Vision System
Regulation Number: 21 CFR 886.4150
Regulation Name: Vitreous Aspiration & Cutting Instrument
Regulatory Class: Class II
Product Code: HQE
Dated: July 23, 2014
Received: July 24, 2014

Dear Mr. Lundberg:

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" (21CFR 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 yours,

Eric A. Mann -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)*

Device Name
CONSTELLATION® Vision System

Indications for Use *(Describe)*
The CONSTELLATION® Vision System is an ophthalmic microsurgical system that is indicated for both anterior segment (i.e. phacoemulsification, removal of cataracts, and intraocular lens injection) and posterior segment (i.e., vitreoretinal) ophthalmic surgery in addition to the indications included with the optional Next Generation laser. 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® 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.

Flex-Tip Laser Probes
• Retinal photocoagulation, panretinal photocoagulation and intravitreal photocoagulation of vascular and structural abnormalities of the retina and choroid including:
  o Proliferative and nonproliferative retinopathy (including diabetic);
  o Choroidal neovascularization secondary to age-related macular degeneration;
  o Retinal tears and detachments;
  o Macular edema;
  o Retinopathy of prematurity;
  o Choroidal neovascularization;
  o Leaking microaneurysms.
• Iridotomy/Iridectomy for treatment of Chronic/Primary Open Angle Glaucoma (COAG,POAG) and Refractory Glaucoma.
• Trabeculoplasty for treatment of Chronic/Primary Open Angle Glaucoma (COAG,POAG) and refractory Glaucoma.
• And other laser treatments including:
  o Internal sclerostomy;
  o Lattice degeneration;
  o Central and Branch Retinal Vein Occlusion;
  o Suturelysis;
  o Vascular and pigmented skin lesions.

UltraVit Probes
• Vitreous aspiration & cutting.
• Membrane cutting & aspiration.
• Lens removal.

Endoilluminator Probes
• Endoillumination

Valved Entry Systems
• Scleral incision
• Canulae for posterior segment instrument access
• Venting (of valved cannulae)

Infusion Cannulas
• Posterior segment infusion (liquid or gas)

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Eric A. Mann -S
2014.08.22 14:24:42 -04'00'

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5 510(K) SUMMARY

The 510(k) Summary is provided here.

This summary is in accordance with 21 CFR 807.92(c).

The submitter of the 510(k) is:

Robert Lundberg
VP, Regulatory Affairs - VGR
Alcon Research Ltd.
20511 Lake Forest Drive
Lake Forest, CA 92630, USA
Phone: (949) 505-7817
Fax: (949) 505-6237

Date Prepared: April 23, 2014

Device Subject to this 510(k):

Trade Name:	CONSTELLATION® Vision System
Common Name:	Vitreous Aspiration & Cutting Instrument/Phacofragmentation System
Classification Name:	Class II Vitreous Aspiration & Cutting Instrument (21 CFR 886.4150) Phacofragmentation System (21 CFR 886.4670)

5.1 Predicate Devices:

The legally marketed device(s) to which Alcon is claiming substantial equivalence are:

510(k) Number	Date Cleared	Device
K101285 K063583	11/12/2010 05/09/2008	CONSTELLATION® Vision System
K121555	12/21/2012	CENTURION® Vision System
K120912	06/15/2012	INFINITI® Vision System

510(k) Number	Date Cleared	Device
K112425 K082845 K021566	11/21/2011 02/12/2009 07/02/2002	
K091777	10/20/2009	Alcon UltraChopper

5.2 Device Description:

The CONSTELLATION® Vision System is designed for use in anterior and posterior procedures that require infusion, vitreous cutting, aspiration, and illumination as well as irrigation, lens emulsification and fragmentation, cautery, diathermy, and IOL Insertion.

5.3 Indications for Use:

The CONSTELLATION® Vision System is indicated for the following:

The CONSTELLATION® Vision System is an ophthalmic microsurgical system that is indicated for both anterior segment (i.e. phacoemulsification and removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery in addition to the indications included with the optional Next Generation laser. 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 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.

Flex-Tip Laser Probes	• Retinal photocoagulation, panretinal photocoagulation and intravitreal photocoagulation of vascular and structural abnormalities of the retina and choroid including: o Proliferative and nonproliferative retinopathy (including diabetic); o Choroidal neovascularization secondary to age-related macular degeneration; o Retinal tears and detachments; o Macular edema; o Retinopathy of prematurity; o Choroidal neovascularization; o Leaking microaneurysms. • Iridotomy/Iridectomy for treatment of Chronic/Primary Open Angle Glaucoma (COAG,POAG) and Refractory Glaucoma. • Trabeculoplasty for treatment of Chronic/Primary Open Angle Glaucoma (COAG,POAG) and refractory Glaucoma. • And other laser treatments including: o Internal sclerostomy; o Lattice degeneration; o Central and Branch Retinal Vein Occlusion; o Suturelysis; o Vascular and pigmented skin lesions.
UltraVit Probes	• Vitreous aspiration & cutting. • Membrane cutting & aspiration. • Lens removal.
Endoilluminator Probes	• Endoillumination
Valved Entry Systems	• Scleral incision • Canulae for posterior segment instrument access • Venting (of valved cannulae)
Infusion Cannulas	• Posterior segment infusion (liquid or gas)

5.4 Brief Summary of Nonclinical Test and Results:

Safety tests of the CONSTELLATION® Vision System have demonstrated its compliance with applicable requirements of the following standards:

Standard #	Title
EN ISO 11135-1: 2007	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

Standard #	Title
AAMI/ANSI/ ISO or EN ISO 11137-1: 2006/(R)2010	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
AAMI/ANSI/ ISO or EN ISO 11137-2: 2012	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
UL 60601-1: 2003	Medical Electrical Equipment, Part 1 – General Requirements for Safety
EN 60601-1: 2006/AC: 2010	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2: 2007/AC: 2010	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC-60601-1-4 - Part 1-4: 2000	General Requirements for Safety - Collateral Standard: Programmable Electric Medical Systems
IEC 60601-1-6: 2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-2-2: 2009	Medical electrical equipment -- Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
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

Biocompatibility evaluations of materials coming in contact with the patient or patient fluid path have been performed to the following standards:

Standard #	Title
ISO 10993-1: 2009	Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing within a Risk management Process
ISO 10993-5: 2009	Biological Evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
ISO 10993-7: 2010	Biological Evaluation of Medical Devices -- Part 7: Ethylene Oxide Sterilization Residuals
ISO 10993-10: 2006	Biological Evaluation of Medical Devices -- Part 10: Tests for Irritation and Delayed-Type Hypersensitivity
ISO 10993-11: 2006	Biological Evaluation of Medical Devices -- Part 11: Tests for Systemic Toxicity

Standard #	Title
ISO 10993-12: 2009	Biological Evaluation of Medical Devices --Part 12: Sample Preparation and Reference Materials

CONSTELLATION® accessories that are provided sterile and intended for single use only are EtO or Gamma sterilized. The sterilization process has been validated per ISO 11135-1: 2007: Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization or per ISO 11137-1: 2006, Sterilization of health care products – Radiation – Part1: Requirements for the development, validation and routine control of a sterilization process for medical devices. Reusable handpieces are provided non-sterile. Validated reprocessing instructions for cleaning, sterilization, and re-use of the handpieces are provided in the Directions for Use of the product.

Technological characteristics affecting clinical performance are similar to those of the predicate devices previously listed. The current CONSTELLATION® Vision System as well as the predicate systems have been developed and manufactured in compliance with 21 CFR 820 and ISO 14971: 2012. Non-clinical testing noted above has demonstrated that the functional requirements have been met and that the modified device is equivalent to the predicate devices.