510(k):
K101285

Alcon
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IRVINE, CA 92816

510(K) SUMMARY

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

The submitter of the 510(k) is:

Martin A. Kaufman
Director, Regulatory Affairs
Alcon Research Ltd.
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NOV 1 3 2010

Date Prepared: November 05, 2010

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)

Predicate Devices

510(k) Number	Device
K063583	Alcon Vision System
K091777	Alcon UltraChopper
K093305	Enhanced UltraVit Probe
K062604	Next Generation Laser

Device Description

The Constellation® Vision System is a combined anterior and posterior procedure ophthalmic system that is modular in design and serves as an enhanced version of the Alcon Vision System. 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 and diathermy. The system was developed with a dual purpose: to make it simple to operate, and to allow the surgeon control and flexibility.

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.

Comparison of the Constellation Vision System to the previously cleared Alcon Vision System (K063583)

The following technical feature was added since clearance of K063583:

- 3D Phaco/Fragmentation control modality – this control modality expanded the user interface to include a screen that allows the operator to apply the same 3D control algorithm to phaco and fragmentation modes as is available in the vitrectomy modes. This capability is the equivalent feature as currently available on the Alcon Accurus® system. This was a software interface change only and included no new hardware.

In addition to the expanded feature set described above, the following product has been cleared since K063583:

- K093305 – Enhanced UltraVit Probe

This version of the Constellation® Vision System has provisions to incorporate the functionality of these added accessory items. All other technical features remain equivalent between the

previously cleared (K063583) version and this current version of the Constellation® Vision System.

Modifications were made to this current version of the Constellation® Vision System to correct anomalies in the hardware and software. These corrections did not introduce new functional capabilities.

Brief Summary of Nonclinical Tests and Results

The Constellation® Vision System conforms to the same standards as were listed in the original K063583 clearance. For this current version of the Constellation® Vision System, regression testing for the Electromagnetic Compatibility (EMC) standard was performed to verify changes made to the touchscreen PCBA.

No other testing was necessary to satisfy compliance to the remaining standards listed in the original Alcon Vision System 510(k), K063583.

Consumables

The Constellation® Vision System consumable products are provided sterile and intended for single use only. These products will be EtO or gamma sterilized and the process will be validated per the standards: EN ISO 11135-1:2007: Sterilization of health care products — Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices or EN ISO 11137-1:2006: Sterilization of Health care Products – Radiation – Part 1: requirements for development, validation, and routine control of a sterilization process for medical devices. Reusable handpieces are not provided sterile. Validated reprocessing instructions for cleaning, sterilization and re-use will be provided in the Directions for Use of the product.

Conclusion

Technological characteristics affecting clinical performance are similar to that of other ophthalmic devices. The Constellation® Vision System has been developed and is manufactured in compliance with FDA and ISO quality system requirements. Test data and documents were submitted that demonstrated that the functional requirements had been met and that the system specifications have been met prior to commercial product release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Alcon Research, Ltd.
c/o Mr. Martin Kaufman
Director, Regulatory Affairs
15800 Alton Parkway
Irvine, CA 92618

NOV 13 2010

Re: K101285
Trade/Device Name: Constellation Vision System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: II
Product Code: HQC
Dated: October 1, 2010
Received: October 4, 2010

Dear Mr. Kaufman:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

NOV 1 3 2010

510(k) Number (if known): k101285

Device Name: Constellation® Vision System

Indications for Use:

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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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