510 (k): K093305

APR - 2 2010

Alcon RESEARCH, LTD.

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Premarket Notification 510(K) Summary

This summary document is being prepared in accordance with section 21 CFR 807.92(c).

The submitter of the 510(k) is:

Martin A. Kaufman
Director, Regulatory Affairs
Alcon Research, Ltd.
15800 Alton Parkway
Irvine, CA 92618
Phone: (949) 753-6250
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Device Subject to this 510(k):

Trade Name:	Enhanced UltraVit Probe
Common Name:	Vitrectomy Probe
Classification Name:	Vitreous aspiration and cutting instrument (886.4150)
Product Code:	MLZ

Predicate Devices

The legally marketed devices(s) to which we are claiming equivalence to are:

510(k) Number	Device
K063583	ALCON® Vision System (CONSTELLATION®) UltraVit Probes

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Device Description

The ALCON Enhanced UltraVit® Probe is a modified vitrectomy probe that will be added to the existing Alcon UltraVit® probe family. The ALCON Enhanced UltraVit® Probe is the same size and shape as existing Alcon vitrectomy probes and is made with the same material as the Alcon UltraVit® probes used on the CONSTELLATION® System (Alcon Vision System, K063583). The ALCON Enhanced UltraVit® Probe will utilize existing packaging configurations and have the same shelf life as existing vitrectomy probes. It will be used with the CONSTELLATION® System. The differences between the enhanced and predicate versions are:

- Increased maximum cut rate.
- Software look-up table changes to accommodate RFID recognition of new probe.
- Parylene N Coating on "O" ring seals.

Indications for Use

The ALCON® Enhanced UltraVit® Probe is intended to be used to remove vitreous and dissect tissue in the eye.

Brief Summary of Non-clinical test and Results

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

Standard #	Title
10993-1: 2003 AAMI/ANSI/ISO	Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing
10993-5: 1999 AAMI/ANSI/ISO	Biological Evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
10993-7:1995 AAMI/ANSI/ISO	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
10993-10:2002/A1:2006 AAMI/ ANSI/ISO	Biological Evaluation of Medical Devices -- Part 10: Tests for irritation and delayed-type hypersensitivity – Including A1:2006
10993-11:2006 AAMI/ANSI/ISO	Biological Evaluation of Medical Devices -- Part 11: Tests for systemic toxicity
10993-12:2007 AAMI/ANSI/ISO	Biological Evaluation of Medical Devices -- Part 12: Sample Preparation and Reference Materials

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The ALCON® Enhanced UltraVit Probe is provided sterile and intended for single use only. This product is Ethylene Oxide sterilized and the process has been validated to a SAL of 10^{-6} per FDA Recognized Consensus Standard – "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.*

Technological characteristics affecting clinical performance are similar to those of predicate devices previously listed. The ALCON® Enhanced UltraVit® Probe has been developed and will be manufactured in compliance with section 21 CFR 820 and ISO 14971:2003. Non-clinical testing has demonstrated that the functional requirements have been met and that the device is equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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Alcon Research, Ltd.
c/o Mr. Martin A. Kaufman
Director, Regulatory Affairs
15800 Alcon Parkway
Irvine, CA 92816

Re: K093305
Trade/Device Name: Enhanced UltraVit Probe
Regulation Number: 21 CFR 886.4150
Regulation Name: Vitreous Aspiration and Cutting Instrument
Regulatory Class: II
Product Code: MLZ
Dated: February 5, 2010
Received: February 5, 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,

Kesia Alexander

for 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

510(k) Number (if known): K093305

Device Name: ALCON® Enhanced UltraVit® Probe

Indications for Use:

The ALCON® Enhanced UltraVit® Probe is indicated to be used to remove vitreous and dissect tissues in the eye.

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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