OCT 17 2011 510(k): K110951

5. PREMARKET NOTIFICATION 510(k) SUMMARY

This 510(k) Summary is provided here and is also included in **Attachment B.**

The submitter of the 510(k) is:

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Director, Regulatory Affairs
Alcon Research, Ltd.
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Devices Subject to this 510(k):

Trade Name: 27+ Retina Instrument Set
Common Name: Vitreoretinal Surgical Accessories
Classification Name: See below

Modified Instrument	21 CFR	Classification name	Class	Product Code	Predicate 510(k)	Date Cleared
27+ UltraVit® Probe	886.4150	Vitreous aspiration and cutting instrument	II	HQE	K093305	04/02/10
27+ Flex-Tip Laser Probe	886.4390	Ophthalmic laser	II	HQB	K062624	11/05/07
27+ Endoilluminator Probe	876.1500	Endoscope and accessories	II	MPA	K063583 K101285	05/09/08 11/12/10
27+ Valved Entry System	886.4350	Manual ophthalmic surgical instrument	I	NGY	n/a	
27+ Infusion Cannula	886.4350	Manual ophthalmic surgical instrument	I	HMX	n/a	

5.1. Predicate Devices:

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

Predicate Date 510(k) Cleared	Predicate Device	Predicate Instrument	Modified Instrument
K093305 04/02/10	Enhanced UltraVit® Probe	25+ UltraVit® Probe	27+ UltraVit® Probe
K062624 11/05/07	Next Generation Laser and accessories (PurePoint® laser)	25+ Flex-Tip Laser Probe	27+ Flex-Tip Laser Probe
K063583 05/09/08 K101285 11/12/10	Alcon Vision System (and accessories) CONSTELLATION® Vision System (and accessories)	25+ Endoilluminator Probe	27+ Endoilluminator Probe
n/a	n/a	25Ga Valved Entry System	27+ Valved Entry System
n/a	n/a	25Ga Infusion Cannula	27+ Infusion Cannula

5.2. Device Description

The five instruments comprising the 27+ Retina Instrument Set are modified versions of approved larger gauge CONSTELLATION accessories but with smaller diameter instrument tips for less invasive surgery. All other features are exactly the same as the respective predicate devices cleared in K093305, K062624, K063583, and K101285.

5.3. Indications for Use:

The 27+ Retina Instrument Set instruments, along with the CONSTELLATION Vision System or Next Generation Laser System, are intended for the following uses:

27+ UltraVit® Probe	• Vitreous aspiration & cutting. • Membrane cutting & aspiration. • Remove a crystalline lens. • Dissect tissues in the eye.
27+ Flex-Tip Laser Probe	• 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. o
27+ Endoilluminator Probe	• Endoillumination
27+ Valved Entry System	• Scleral incision
27+ Infusion Cannula	• Posterior segment infusion

5.4. Brief Summary of Nonclinical 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: 2009 AAMI/ANSI/ISO	Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within the Risk Management Process
10993-5: 2009 AAMI/ANSI/ISO	Biological Evaluation of Medical Devices -- Part 5: Tests for In Vitro Cytotoxicity
10993-7: 2008 AAMI/ANSI/ISO	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals
10993-10: 2002/R:2008 AAMI/ANSI/BE78	Biological Evaluation of Medical Devices -- Part 10: Tests for Irritation and Delayed-type Hypersensitivity
10993-10:2009 EN ISO	Biological Evaluation of Medical Devices - Part 10:Tests for Irritation and Delayed –type Hypersensitivity
10993-11:2009 AAMI/ANSI/ISO	Biological Evaluation of Medical Devices -- Part 11: Tests for systemic toxicity
10993-12:2009 AAMI/ANSI/ISO	Biological Evaluation of Medical Devices --Part 12: Sample Preparation and Reference Materials

These accessories are provided sterile and are intended for single use only. These products are EO 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 the development, validation, and routine control of a sterilization process for medical devices.*

Technological characteristics affecting clinical performance are similar to that of predicate devices previously listed. The 27+ Retina Instrument Set has been developed and will be manufactured in compliance with 21 CFR 820 and ISO 14971:2007. Non-clinical testing noted above has demonstrated that the functional requirements have been met and that the modified devices are equivalent to the predicate devices.

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, RAC
Director, Regulatory Affairs
15800 Alton Parkway
Irvine, CA 92816

OCT 17 2011

Re: K110951
Trade/Device Name: 27+ Retina Instrument Set
Regulation Number: 21 CFR 886.4150
Regulation Name: Vitreous aspiration and cutting instrument
Regulatory Class: II
Product Codes: HQE, HMX, HQB, MPA, NGY
Dated: October 6, 2011
Received: October 7, 2011

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. 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 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): K110951

Device Name: 27+ Retina Instrument Set

Indications for Use:

The 27+ Retina Instrument Set instruments, along with the Constellation Vision System or Next Generation Laser System, are intended for the following uses:

27+ UltraVit Probe	• Vitreous aspiration & cutting. • Membrane cutting & aspiration. • Lens removal. • Dissect tissue in the eye. (The 27+ UltraVit Probe is intended to be used with the Alcon Constellation Vision System.)
27+ Flex-Tip Laser Probe	• 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. (The 27+ Flex-Tip Probe is intended to be used with 532 nm laser systems such as the Alcon Constellation Vision System, or the Alcon PurePoint Laser System.)

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Nose and Throat Devices

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27+ Endoilluminator Probe	• Endoillumination (The 27+ Endoilluminator Probe is intended to be used with the Alcon Constellation Vision System)
27+ Valved Entry System	• Scleral incision • Canulae for posterior segment instrument access • Venting (of valved cannulae)
27+ Infusion Cannula	• Posterior segment infusion (liquid or gas)

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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