510(k): k121555

DEC 2 1 2012

5. PREMARKET NOTIFICATION 510(k) SUMMARY

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

The submitter of the 510(k) is:

Charles Ogbonna BSc, PhD, MBA.
Assistant Director, Regulatory Affairs
Alcon Research, Ltd.
18500 Alton Parkway
Irvine, CA 92618
Phone: (949) 753-6307
Fax: (949) 753-6237

Device Subject to this 510(k):

Trade Name:	CENTURION® Vision System
Common Name:	Phacofragmentation System
Classification Name:	Phacofragmentation System (per 21 CFR 886.4670)

5.1 Predicate Devices:

The legally marketed devices to which we are claiming equivalence to are:

Predicate Device	510 (k) number	Predicate Cleared Date
Alcon INFINITI® Vision System (Evergreen II)	K112425	11/21/2011
CONSTELLATION® Vision System	K101285	11/12/2010
Alcon Enhanced UltraVit® Probe	K093305	04/02/2010
Alcon UltraChopper® Tip	K091777	10/20/2009
INFINITI® w/OZil® IP	K082845	02/12/2009
Bausch & Lomb Microsurgical System (Stellaris)	K082473	01/05/2009
Alcon Vision System	K063583	05/09/2008
AMO Ophthalmic Surgical System (Whitestar Signature)	K060366	04/07/2006
Gemini Ophthalmic Surgical System (ACCURUS®)	K911808	06/25/1991

5.2 Device Description

The CENTURION® Vision System is a phacofragmentation system similar to the Alcon INFINITI® Vision System (Evergreen II - K112425). It is designed 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 intra-ocular lens injection.

5.3 Indications for Use:

The CENTURION Vision system 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 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.

5.4 Brief Summary of Nonclinical test and Results:

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

Standard #	Title
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.
ISO 11137-1: 2006	Sterilization of health care products – Radation-Part1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
ISO 11137-2: 2007	Sterilization of health care products – radiation – Part2: Establishing the sterilization dose.

Standard #	Title
BS EN ISO 11979-3: 2006	Ophthalmic implants – Intraocular Lenses – Part 3: Mechanical properties and test methods
EN ISO 14971: 2007	Medical Devices: Application of Risk Management to Medical Devices
IEC 60601-1: 2005, A2: 1995	Medical Electrical Equipment - Part 1: General requirements for safety
IEC 60601-1-1: 2000	Medical electrical equipment. Part 1-1: General requirement for safety -- Collateral standard: Safety requirements for medical electrical systems
EN 60601-1-2: 2007	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-4: 1999	Medical electrical equipment - Part 1: General requirements for safety – 4. Collateral standard: Programmable electrical medical systems (IEC 60601-1-4:1996/A1:1999)
IEC 60601-1-6: 2010	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability.
IEC 60601-2-2: 2009	Medical electrical equipment - Part 2: Particular requirements for the safety of high frequency surgical equipment.
IEC 80601-2-58: 2008	Medical electrical equipment – Part 2-58: Particular requirements for 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
ISO 10993-12: 2009	Biological Evaluation of Medical Devices --Part 12: Sample Preparation and Reference Materials

Centurion® 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 *Centurion*® Vision System 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 device is equivalent to the predicate devices.

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

December 21, 2012

Alcon Research, Ltd.
Attention: Charles Ogbonna BSc, PhD, MBA
Assistant Director, Regulatory Affairs
18500 Alton Parkway
Irvine, CA 92618

Re: K121555
Trade/Device Name: CENTURION® Vision System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQC
Dated: October 12, 2012
Received: October 15, 2012

Dear Dr. Ogbonna:

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,

Victor Krauthamer -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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121555

Device Name: CENTURION® Vision System

Indications for Use:

The CENTURION® Vision System 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 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.

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 and Ear, Nose and Throat Devices
510(k) Number K121555