NOV 2 1 2011 510(k): k112425

Alcon

PREMARKET NOTIFICATION 510(k) SUMMARY

The submitter of the 510(k) is:

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Device Subject to this 510(k):

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

Predicate Devices:

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

510(k) Number	Device
K021566	Infiniti® Vision System
K082845	Infiniti® Vision System with OZil® IP
K091777	Alcon UltraChopper Tip
K093210	AquaLase Capsule Wash Tip
K063155	Monarch III IOL Delivery System

Device Description

The *Infiniti® Vision System* is an enhanced version of the *Infiniti® Vision System with OZil® IP* (K082845) that is modular in design and incorporates the *Power Watch* feature, along with the Alcon UltraChopper Tip, the AquaLase Capsule Wash Tip, the AutoSert™ IOL Injector, and its associated software.

Indications for Use:

The *Infiniti® Vision System* is indicated for emulsification, separation, and removal of cataracts, the removal of residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intra-ocular lens injection. The AutoSert™ IOL Injector Handpiece is intended to deliver qualified AcrySof® intraocular lenses into the eye following cataract removal.

The following system modalities additionally support the described indications:

- Ultrasound with UltraChopper Tip achieves the functionality of cataract separation.
- AquaLase achieves the functionality for removal of residual cortical material and lens epithelial cells
- The AutoSert™ IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The AutoSert™ is indicated for use with ACRYSOF lenses SN60WF and SN6AD1, as well as approved Acrysof lenses that are specifically indicated for use with this inserter, as indicated in the approved labeling of those lenses.

Brief Summary of Nonclinical test and Results:

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

Standard #	Title
11135-1:2007 ISO	Sterilization of health care products – Ethylene oxide – Requirements for development, validation, and routine control of a sterilization process for medical devices.
11979-3:2006 BS EN ISO	Ophthalmic implants – Intraocular Lenses – Part 3: Mechanical properties and test methods
14971:2007 EN ISO	Medical Devices: Application of Risk Management to Medical Devices
IEC 60601-1: 1988, A1:1991, 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: 2004	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-4: 2000	Medical electrical equipment - Part 1: General requirements for safety – 4. Collateral standard: Programmable electrical medical systems.
IEC 60601-1-6: 2006	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability.
IEC 60601-2-2: 2006	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 10993-10: 2002/A1:2006	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: 2007	Biological Evaluation of Medical Devices --Part 12: Sample Preparation and Reference Materials

Many Infiniti® accessories are provided sterile and are intended for single use only. These products are EtO sterilized and the process has been validated per ISO 11135-1:2007: Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization. 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 that of predicate devices previously listed. The *Infiniti® 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 device.

Accessories Provided with the System (subject to change)

Configurations of tips and sleeves currently used with the Irrigation/Aspiration Handpiece. Description
ASSY, SHIP, INTREPID POLYMER I/A TIP, STRAIGHT
ASSY, SHIP, INTREPID POLYMER I/A TIP, ANGLED
ASSY, SHIP, INTREPID POLYMER I/A TIP, CURVED
I/A Tip 0.5 mm
I/A Tip 0.2 mm
I/A Tip 0.3 mm Small Bore
I/A Tip 0.3 mm Small Bore Mod
I/A Tip 0.3 mm Bent
I/A Tip 0.3 mm Bent & Sand Blast
I/A Tip .033 OD, .3mm, Intrepid

Configurations of tips and sleeves currently used with the Irrigation/Aspiration Handpiece. **Description**
I/A Tip .033 OD, .3mm Bent, Intrepid
Silicone I/A Tip, Bent
Silicone I/A Tip, Straight
Ultraflow Tool/O-rings
Ultraflow IA Handpiece Comp
Ultraflow IA Handpiece Only
Ultraflow IA Tip STR
Ultraflow IA Tip CRVD
Ultraflow IA 45
Ultraflow IA 90
Ultraflow IA 120
Ultraflow CNL STTL
Ultraflow Luer
Straight Tip, 3 mm
Ultraflow Tip Protector, Standalone
45° Bent Tip, .3 mm
90° Bent Tip, .3mm
Irrigation Only Luer
Curved Tip, .3mm
Threaded Tip - STTL
Ultraflow I/A Box
Replacement O-ring

Configurations of Paks currently used with the Infiniti Vision System.

Description
Ultrasound FMS, Basic
Ultrasound FMS, Tipless, 0.9mm
Ultrasound FMS, Tipless, 1.1mm
Ultrasound FMS, Tipless, 0.9mm HIS
Ultrasound FMS, Tipless, 1.1mm HIS
Ultrasound FMS, 30° Round, 0.9 mm ABS
Ultrasound FMS, 45° Round, 0.9 mm ABS
Ultrasound FMS, 30° Kelman, 0.9 mm ABS
Ultrasound FMS, 45° Kelman, 0.9 mm ABS
Ultrasound FMS, 30° Round, 1.1 mm ABS
Ultrasound FMS, 45° Round, 1.1 mm ABS
Ultrasound FMS, 30° Kelman, 1.1 mm ABS
Ultrasound FMS, 45° Kelman, 1.1 mm ABS
Ultrasound FMS, 30° Round, 0.9 mm MicroTip Flared ABS
Ultrasound FMS, 45° Round, 0.9 mm MicroTip Flared ABS
Ultrasound FMS, 30° Kelman, 0.9 mm MicroTip Flared ABS
Ultrasound FMS, 45° Kelman, 0.9 mm MicroTip Flared ABS

Description
Ultrasound FMS, 30° Round, 1.1 mm Flared ABS
Ultrasound FMS, 45° Round, 1.1 mm Flared ABS
Ultrasound FMS, 30° Kelman, 1.1 mm Flared ABS
Ultrasound FMS, 45° Kelman, 1.1 mm Flared ABS
Ultrasound FMS, 30° Round, 0.9 mm Mackool
Ultrasound FMS, 45° Round, 0.9 mm Mackool
Ultrasound FMS, 30° Kelman, 0.9 mm Mackool
Ultrasound FMS, 45° Kelman, 0.9 mm Mackool
Ultrasound FMS, 30° Round, 1.1 mm Mackool Flared ABS
Ultrasound FMS, 45° Round, 1.1 mm Mackool Flared ABS
Ultrasound FMS, 30° Kelman, 1.1 mm Mackool Flared ABS
Ultrasound FMS, 45° Kelman, 1.1 mm Mackool Flared ABS
Ultrasound FMS, 30° Round, 0.9 mm Tapered ABS
Ultrasound FMS, 45° Round, 0.9 mm Tapered ABS
Ultrasound FMS, 30° Kelman, 0.9 mm Tapered ABS
Ultrasound FMS, 45° Kelman, 0.9 mm Tapered ABS
Ultrasound FMS, Tipless, 0.9 Ultra
Ultrasound FMS, 30° Kelman, 0.9 mm Mini Flared ABS, Ultra
Ultrasound FMS, 45° Kelman, 0.9 mm Mini Flared ABS, Ultra
Ultrasound FMS, 30° OZil 12, 0.9 mm Mini Flared ABS, Ultra
Ultrasound FMS, 45° OZil 12, 0.9 mm Mini Flared ABS, Ultra
Ultrasound FMS, 30° Kelman, 0.9 mm Mini Flared ABS
Ultrasound FMS, 45° Kelman, 0.9 mm Mini Flared ABS
Ultrasound FMS, 30° OZil 12, 0.9 mm Mini Flared ABS
Ultrasound FMS, 45° OZil 12, 0.9 mm Mini Flared ABS
Ultrasound FMS, Tipless, 0.9mm J
Ultrasound FMS, Tipless, 1.1mm J
Ultrasound FMS, Tipless, 0.9mm HIS J
Ultrasound FMS, Tipless, 1.1mm HIS J
Ultrasound FMS, Tipless, 0.9 Ultra J
Ultrasound FMS, Intrepid, Basic
Ultrasound FMS, Intrepid, Tipless, 0.9 Ultra
Ultrasound FMS, Intrepid, Tipless, 1.1 Ultra
Ultrasound FMS, Intrepid, Tipless, 0.9 Nano
Ultrasound FMS, Intrepid, Tipless, 1.1 Nano
Ultrasound FMS, Intrepid, 30° Kelman, 0.9 mm Mini-Flared ABS, Ultra
Ultrasound FMS, Intrepid, 45° Kelman, 0.9 mm Mini-Flared ABS, Ultra
Ultrasound FMS, Intrepid, Tipless, 0.9
Ultrasound FMS, Intrepid, 30° Kelman, 0.9 mm Mini Flared ABS, Nano
Ultrasound FMS, Intrepid, 45° Kelman, 0.9 mm Mini Flared ABS, Nano
Ultrasound FMS, Intrepid, 30° OZil 12, 0.9 mm Mini Flared ABS, Nano
Ultrasound FMS, Intrepid, 45° OZil 12, 0.9 mm Mini Flared ABS, Nano
Ultrasound FMS, Intrepid, 30° OZil 12, 0.9 mm Mini Flared ABS, Ultra

Description
Ultrasound FMS, Intrepid, 45° OZil 12, 0.9 mm Mini Flared ABS, Ultra
Ultrasound FMS, Intrepid, 30° Kelman, 0.9 mm Mini Flared ABS, 0.9
Ultrasound FMS, Intrepid, 45° Kelman, 0.9 mm Mini Flared ABS, 0.9
Ultrasound FMS, Intrepid, 30° OZil 12, 0.9 mm Mini Flared ABS, 0.9
Ultrasound FMS, Intrepid, 45° OZil 12, 0.9 mm Mini Flared ABS, 0.9
Ultrasound FMS, Intrepid, Basic, J
Ultrasound FMS, Intrepid, Tipless, 0.9 Ultra, J
Ultrasound FMS, Intrepid, Tipless, 1.1 Ultra, J
Ultrasound FMS, Intrepid, Tipless, 0.9 Nano, J
Ultrasound FMS, Intrepid, Tipless, 1.1 Nano, J
Ultrasound FMS, Intrepid, Tipless, 0.9 J
INFI, Multipak, Basic Pak
INFI, Multipak, 0.9mm Tipless
INFI, Multipak, 1.1mm Tipless
INFI MP Procedural Pouch Basic
INFI MP Procedural Pouch 0.9mm
INFI MP Procedural Pouch 1.1mm
Infiniti MP Drain Bags
INFI Multi-Pak Basic Stand Alone
INFI Multi-Pak 0.9 Tipless Stand Alone
INFI Multi-Pak 1.1 Tipless Stand Alone
Ultrasound FMS, Intrepid Plus, Basic
Ultrasound FMS, Intrepid Plus, 0.9 MM Tipless Ultra
Ultrasound FMS, Intrepid Plus, 1.1 MM Tipless Ultra
Ultrasound FMS, Intrepid Plus, 0.9 MM Tipless Nano
Ultrasound FMS, Intrepid Plus, 1.1 MM Tipless Nano
Ultrasound FMS, Intrepid Plus, 0.9 MM Mini-Flared ABS 30K, Ultra
Ultrasound FMS, Intrepid Plus, 0.9 MM Mini-Flared ABS 45K, Ultra
Ultrasound FMS, Intrepid Plus, 0.9 MM Tipless
Ultrasound FMS, Intrepid Plus, 0.9 MM Mini-Flared ABS 30K, Nano
Ultrasound FMS, Intrepid Plus, 0.9 MM Mini-Flared ABS 45K, Nano
Ultrasound FMS, Intrepid Plus, 0.9 MM Mini-Flared ABS 30 OZil, Nano
Ultrasound FMS, Intrepid Plus, 0.9 MM Mini-Flared ABS 45 OZil, Nano
Ultrasound FMS, Intrepid Plus, 0.9 MM Mini-Flared ABS 30 OZil, Ultra
Ultrasound FMS, Intrepid Plus, 0.9 MM Mini-Flared ABS 45 OZil, Ultra
Ultrasound FMS, Intrepid Plus, 0.9 MM Mini-Flared ABS 30K
Ultrasound FMS, Intrepid Plus, 0.9 MM Mini-Flared ABS 45K
Ultrasound FMS, Intrepid Plus, 0.9 MM Mini-Flared ABS 30 OZil
Ultrasound FMS, Intrepid Plus, 0.9 MM Mini-Flared ABS 45 OZil

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

NOV 2 1 2011

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

Re: K112425
Trade/Device Name: Infiniti Vision System (Evergreen II)
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: II
Product Codes: HQC, HQR, MLZ, KYB
Dated: August 19, 2011
Received: August 23, 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,

Keosia 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): K112425

Device Name: *Infiniti® Vision System*

Indications for Use:

The *Infiniti® Vision System* is indicated for emulsification, separation, and removal of cataracts, the removal of residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intra-ocular lens injection. The AutoSert™ IOL Injector Handpiece is intended to deliver qualified AcrySof® intraocular lenses into the eye following cataract removal.

The following system modalities additionally support the described indications:

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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

510(k) Number K112425