MAR - 4 2010

Alcon

K093210

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.
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Device Subject to this 510(k):

Trade Name:	AquaLase® Capsule Wash Tip
Common Name:	Accessory to a Phacoemulsification Device
Classification Name:	Accessory to a Phacofragmentation Device (per 21 CFR 886.4670)

1. Predicate Devices

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

510(k) Number	Device
K980292/K021566	AquaLase® 1.1 mm Liquefaction Tip
K911808/K910245	ALCON® Silicone I/A Tip
K030957	Milvella Perfect capsule

2. Device Description

The AquaLase® Capsule Wash Tip is a sterile, single-use product. It is an accessory to the AquaLase® Handpiece (K980292), which produces the heated intraocular irrigating solution (Balanced Salt Solution or equivalent fluid) that washes the capsular surface. The AquaLase® Capsule Wash Tip and the AquaLase® Handpiece are accessories to the INFINITI® Vision System (K021566). The AquaLase® Capsule Wash Tip utilizes existing packaging configurations and has the same shelf life as existing AquaLase® tips.

To use the AquaLase® Capsule Wash Tip as intended, no modification to the existing INFINITI® System is required.

3. Indications for Use

The AquaLase® Capsule Wash Tip is indicated to assist in the removal of residual cortical material and lens epithelial cells.

4. 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
10993-7:2008 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

The AquaLase® Capsule Wash tip 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 – ""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."

Technological characteristics affecting clinical performance are similar to those of predicate devices previously listed. The AquaLase® Capsule Wash Tip 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.

5. Summary of Performance Testing

The AquaLase® Capsule Wash Tip has been developed and manufactured in compliance with recognized international consensus standards and FDA regulations/ guidance documents. Performance testing demonstrates that the AquaLase® Capsule Wash Tip operates as intended on the INFINITI® Vision System and is substantially equivalent to the predicate device. Salient tip performance characteristics such as fluid output volume and fluid output temperature are analogous to the 1.1mm Liquefaction Tip. The fluid output profile is modified from the 1.1mm Liquefaction Tip; the Capsule Wash Tip's profile is to better serve the intended use.

Performance test results are provided in the following table.

Results Summary for AquaLase® Capsule Wash Tip (CW Tip)

Test Description	Results
Nozzle and Tube Retention	Tips passed the minimum retention strength.
Passive Flow	Tips passed the passive flow requirements.
Wrench/Tip Detachment	Tips passed the wrench/tip detachment force.
Fluid Output Profile	Tips passed the fluid output profile requirement of being collimated.
Handpiece Compatibility	Tips passed the handpiece compatibility requirement.
Irrigation Free Flow	Tips passed the minimum irrigation free flow rate requirement.
Injection Fluid Active Flow (Average Pulse Flow Rate)	Tips passed the injection fluid active flow.
Injection Pulse Volume	Tips passed the maximum injection pulse volume requirement.
Pulse Fluid Exit Temperature	Tips passed the maximum temperature requirement.
Leakage	Tips passed the requirement to remain leak free during use.
Particulates	Tips passed the metallic particulate requirements.
Endurance	Tips passed the endurance requirement for Injection Fluid Active Flow and the endurance requirement for Leakage

For this table, the predicate device is the 1.1mm AquaLase® Liquefaction Tip (K980292/ K021566).

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAR - 4 2010

Alcon Research, Ltd.
c/o Mr. Martin A. Kaufman, RAC
Director, Regulatory Affairs
15800 Alton Parkway
Irvine, CA 92816-3818

Re: K093210
Trade/Device Name:AquaLase® Capsule Wash Tip
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System (Accessory)
Regulatory Class: Class II
Product Code: HQC
Dated: January 28, 2010
Received: January 29, 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. 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,

Keoia 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

4. Indications for Use Statement

The Indications for Use statement is provided here and is also included in **Attachment A**.
The AquaLase® Capsule Wash Tip is intended for prescription use only.

510(k) Number (if known): K093210

Device Name: AquaLase® Capsule Wash Tip

Indications for Use:

The AquaLase® Capsule Wash Tip is indicated to assist in the removal of residual cortical material and lens epithelial cells.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K093210