K021566

JUL - 2 2002

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:

Michael Buenger
Associate Director, Regulatory Affairs
Alcon Research, Inc.
6201 South Freeway
Fort Worth, TX 76132
Phone: (817) 551-6810
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Date Summary Prepared: May, 1, 2002

Device Subject to this 510(k)

Trade Name:	*Infiniti*™ Cataract Extraction System
Common Name:	Phacofragmentation System
Classification Name:	Phacofragmentation System (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
K911808	Gemini Ophthalmic Surgery System (Marketed as the *Series 20000*® *Legacy*® (STTL) and *Accurus*®)
K981116	Sovereign* Cataract Extraction System
K961310	Storz *Premiere** II Microsurgical System
K980292	Cataract Liquefracture Device (Marketed as *AquaLase*™)
K925631	*Phacotron Gold** Multifunction Ultrasonic (*Tmesis**) Handpiece

2. **Device Description**

The *Infiniti*™ is a cataract extraction system used by ophthalmologists during cataract surgery. It is designed for use in anterior segment procedures that require simultaneous lens fragmentation, irrigation and aspiration, as well as ancillary functions such as vitreous aspiration and cutting along with bipolar coagulation. The *Infiniti*™ system is a modification of the Alcon *Series 20000*™ *Legacy*® system and is substantially equivalent to the predicate devices listed above.

3. **Indications for Use:**

The intended use of the device is emulsification and removal of cataracts, as well as associated procedures such as vitreous aspiration and cutting along with bipolar coagulation.

4. **Brief Summary of Nonclinical test and Results:**

Safety tests of the *Infiniti*™ Cataract Extraction System will demonstrate its compliance with applicable requirements of the following standards:

IEC 60601-1: 1988	Medical Electrical Equipment, Part 1 – General Requirements for Safety.
IEC 60601-1: A1:1991-11 + A2:1995 –03	Amendment - Medical Electrical Equipment, Part 1 – General Requirements for Safety
IEC 60601-1-2 :1993	Medical electrical equipment Part 1: General Requirements for Safety 2. Collateral Standard: ElectroMagnetic Compatibility – Requirements and tests.
UL 2601-1: 1997	Medical Electrical Equipment, Part 1 – General Requirements for Safety

Biocompatibility evaluations of materials coming in contact with the patient or patient fluid path in the *Infiniti*™ system will be performed to the following standards:

AAMI/ ANSI/ ISO 10993-1: 1997	Biological evaluation of medical devices, Part 1: Evaluation and Testing
AAMI/ ANSI/ ISO 10993-5: 1999	Biological evaluation of medical devices, Part 5: Test for cytotoxicity: in vitro methods.
AAMI/ ANSI/ ISO 10993-7: 1995	Biological evaluation of medical devices, Part 7: Ethylene oxide sterilization methods.
AMI/ ANSI/ ISO 10993-10: 1995	Biological evaluation of medical devices, Part 10: Tests for irritation and sensitization.

The *Infiniti*™ consumable products are provided sterile and intended for single use only. These products will be EtO sterilized and the process will be validated per the standard: AAMI/ ISO 11135:1994: Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization. Reusable handpieces are not provided sterile. Validated reprocessing instructions for cleaning, sterilization and re-use will be 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*™ Cataract Extraction System will be developed and manufactured in compliance with FDA and ISO quality system requirements. Testing will demonstrate that the functional requirements have been met and that the system specifications are fulfilled prior to commercial product release.

Trademark References:

*PHACOTRON GOLD is a registered trademark of Chiron Corporation
*PREMIERE is a registered trademark of Storz Ophthalmics, Inc. Corp.
*SOVEREIGN is a registered trademark of Allergan, Inc. Corp.
*TMESIS is a registered trademark of Azia Y. Anis
*SYNERGIST is a registered trademark of Chiron Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

Alcon Research, Ltd.
c/o Mr. Michael Buenger
Associate Director, Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K021566
Trade/Device Name: Infiniti™ Cataract Extraction System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: II
Product Code: HQC; HQR; MLZ
Dated: May 10, 2002
Received: May 13, 2002

Dear Mr. Buenger:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K021566

Device Name: Infiniti™ Cataract Extraction System

Indications for Use:

The intended use of this device is emulsification and removal of cataracts, as well as associated procedures such as vitreous aspiration and cutting along with bipolar coagulation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

Donna R Lechner for DMW/ARR

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K021566

(Optional Format 3-10-98)