K981103

JUN 23 1998

March 20, 1998

510(K) SUMMARY

Submitted by:

Martin A. Kaufman
Manager, Regulatory Affairs, Surgical Devices
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76132
(817) 551-8388 (Phone)
(817) 551-4630 (Fax)

Trade Name:	Alcon Limited Reuse Ultrasonic Tip
Common Name	Alcon Limited Reuse Ultrasonic Tip
Classification Name	Phacofragmentation System (per 21 CFR 886.4670)

K981103

1. Predicate Device

We are claiming equivalence of the Alcon Limited Reuse tip to the phacoemulsification ultrasonic tips used in the following legally marketed devices:

Predicate Devices	510(k) Title	Manufacturer
K911808	Alcon Series 20,000® Legacy®	Alcon Surgical
K851210	United Sonics Phaco Module Model PF-35	United Sonics, Inc.
K902876	Phacotron Systems Plus III Phacoemulsifier Aspirator	Intraoptics Surgical
K915456	United Sonics Phaco 3000 Linear	Innovative Medical Systems
K915457	United Sonics Phaco 20/20 System I	"
K921460	Storz Premiere™/ Premiere™ Microvit®	Storz Instrument Company
K921758	Storz Protege™ Ophthalmic Microsurgical System	"
K925631	Phacotron Gold™ Multifunction Ultrasonic Handpiece	Chiron IntraOptics

2. Device Description

The Series 20000® Legacy® System and its predicate devices use ultrasonic energy to emulsify cataractous lens material and remove it from the eye (phacoemulsification). Electronic energy is generated in the machine, delivered to a handpiece and is finally converted to ultrasonic energy delivered through a hollow titanium needle, or tip. Irrigation fluid is delivered to the eye via the combination of an irrigation sleeve over the handpiece tip. The emulsified lens material is aspirated out of the eye through the center of the handpiece/tip assembly. The handpieces are being routinely used repeatedly in multiple surgical procedures, while the tips marketed by Alcon have been labeled for single-use only. Other predicate devices have been labeled as reusable. The labeling modification which is the subject of this submission is that some of Alcon phacoemulsification tips can be used in up to 20 surgical procedures, provided they are carefully handled and inspected before and after each use.

3. Intended Use of the Device

The intended use of this device is to assist in the automated phacoemulsification of a natural crystalline lens.

4. Summary of the Technological Characteristics of the Device

The Alcon Limited Reuse Tips utilizes the same technology as the predicate devices. The tips are manufactured from a titanium alloy which exhibits excellent structural and chemical properties making it suitable for repeated use in surgical procedures.

K981103

5. Summary of the Performance Data

It has been demonstrated that repeated use of the phacoemulsification tips does not alter performance of the tips as to affect safety and efficacy of the device. Specifically, effects of fatigue, cavitation erosion, and chemical reactions have been shown to have no significant effect on tip performance.

6. Conclusions

Therefore, based on the data provided in this Premarket notification, the Alcon Limited Reuse Phacoemulsification Ultrasonic Tip is proven to be substantially equivalent to the predicate devices described in Section 1 (above).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 1998

Martin A. Kaufman
Manager, Regulatory Affairs, Surgical Devices
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76132

Re: K981103
Trade Name: Turbosonics Limited Reuse Ultrasonic Tip
Regulatory Class: II
Product Code: 86 HQC
Dated: March 20, 1998
Received: March 26, 1998

Dear Mr. Kaufman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) Number (if known): K981103

K981103

Device Name: Limited Reuse Ultrasonic Tips.

Indications For Use:

The intended use of this device is to assist in the automated phacoemulsification of a natural crystalline lens.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bruce Drum

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K981103

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)