MAY 19 1998

K980292

Alcon
LABORATORIES

ALCON LABORATORIES, INC.
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January 21, 1998

510(K) SUMMARY

Submitted by:

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Manager, Regulatory Affairs, Surgical Devices
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76132
(817) 551-8388 (Phone)
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Trade Name:	TBD
Common Name	Cataract Liquefracture Device
Classification Name	Phacofragmentation System (per 21 CFR 886.4670)

K980292

1. Predicate Device

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

Phacoemulsification function associated with Alcon's:
K911808, Gemini Ophthalmic Surgery System (being marketed as the Series 20,000® Legacy® (STTL)).

Automated HydroSonics® function:
K902798

2. Device Description

The Liquefracture device is designed to assist ophthalmic surgeons in the removal of cataractous lenses (cataracts) for the purpose of restoration of impaired sight due to the formation of a cataract. Currently, their are two common methods used to complete this procedure. The first is to remove the lens in its entirety or in large sections by manually grasping and explanting (extracapsular cataract extraction or ECCE). The second is to use ultrasound to fragment the cataract into small pieces that are simultaneously drawn out of the eye through an aspiration tube (phacoemulsification). Alcon has developed and marketed a cataract pretreatment method (Automated HydroSonics®) to improve the efficiency of ultrasonic phacoemulsification.

The Liquefracture device combines the pretreatment and emulsification functions.. It will be packaged into a handpiece used directly by the surgeon within the sterile field. The handpiece will be driven by a Ophthalmic Surgery system containing irrigation and aspiration functions as currently provided in cataract surgery equipment. In addition, a low power DC power source will be included in the Ophthalmic Surgery system to control the fluid heating function of the handpiece. A user interface will also be provided by the Ophthalmic Surgery system, which is placed external to the sterile environment (field) just as in most cataract surgery equipment.

3. Intended Use of the Device

This device assists in the removal of cataracts by softening, emulsifying and aspirating the cataract.

4. Summary of the Technological Characteristics of the Device

The Automated HydroSonics® instrument is marketed and used to soften a cataract allowing easier ultrasonic emulsification. The mechanism for this softening is a delamination of the layers of the cataract. By increasing the temperature of the delivered fluid and by improving the efficiency of the fluid delivery, not only is the cataract delaminated, the layers are fragmented into portions that are easily aspirated using similar aspiration parameters currently used in phacoemulsification.

The Liquefracture handpiece containing BSS injection and I/A capability is inserted into the eye. The heated BSS pulses are directed at the cataract while aspiration is engaged to remove emulsified material. Irrigation is also utilized to maintain space and pressure in the anterior segment of the eye.

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The heated BSS pulses are created by heating and pressurizing a small volume of fluid within the handpiece. Controlled volumetric infusion of heated BSS is then expressed out of the handpiece when activated by the operator (surgeon).

The heated BSS pulses affect the cataract in the same manner as ultrasound. With ultrasound, the vibrating tip creates forward moving pressure waves which impact the cataract causing fragmentation. For the Liquefracture device, the heated BSS exits the handpiece lumen in pressure waves causing the same fragmentation result when they impact the cataract.

5. Summary of the Performance Data

The testing and calculations provided in this Premarket notification show the device to be as safe and effective in the removal of cataracts as the predicate devices. Specifically, the anterior chamber temperature rise, the histological impact of hot BSS pulses in vivo and the efficiency of cataract aspiration are all comparable to U/S phacoemulsification.

6. Conclusions

Therefore, based on the data provided in this Premarket notification, the Alcon Cataract Liquefracture Device has been shown to be substantially equivalent to predicate devices such as those devices described in Item 1 (above).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 1998

Mr. Martin A. Kaufman
Manager, Regulatory Affairs
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K980292
Trade Name: Cataract Liquefracture Device
Regulatory Class: II
Product Code: 86 MUS
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): K980292

Device Name: Cataract Liquefracture Device.

Indications For Use:

This device assists in the removal of cataracts by softening, emulsifying and aspirating the cataract

(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 Devices
510(k) Number K980292

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

(Optional Format 1-2-96)