November 25, 1997

K973332

510(K) SUMMARY

DEC - 2 1997

Submitted by:

Michael E. Pfleger
Associate Director, Regulatory Affairs
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134-2099
(817) 551-4877 (Phone)
(817) 551-4630 (Fax)

Device Name:

Common Name: Contact Lens Care Multi-Purpose Solution

Proprietary Name: Alcon Multi-Purpose Disinfecting Solution ID 90746

Indications for Use:

For the daily cleaning, rinsing, disinfecting and storing of soft (hydrophilic) contact lenses. For use in chemical (not heat) disinfection. Alcon Multi-Purpose Solution ID 90746 can also be used as a diluent for OPTI-ZYME® Enzymatic Cleaner.

Description:

Alcon Multi-Purpose Disinfecting Solution ID 90746 is a sterile, buffered, isotonic, aqueous solution containing sodium citrate, sodium chloride, boric acid, sorbitol, AMP-95, tetronic 1304, with edetate disodium 0.05%, Polyquad (polyquaternium-1) 0.0001% and AL-6289 0.0005% as preservatives.

Substantial Equivalence:

Alcon Multi-Purpose Disinfecting Solution ID 90746 is substantially equivalent in terms of its actions and indications to Alcon OPTI-FREE® Multi-Purpose Solution and Alcon OPTI-ONE® Multi-Purpose Solution. These two products were cleared for marketing under P830034/S27 and P830034/S26 respectively.

Alcon Multi-Purpose Disinfecting Solution ID 90746 meets the guidelines set forth in FDA's May 1, 1997 Guidance for Industry - Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.

Safety and Effectiveness:

A. Non-Clinical Data

Microbiological Studies

The product was evaluated for microbiological safety and effectiveness using the FDA Guidelines for contact lens solutions.

- The formulation meets the Stand-Alone criteria for disinfection of contact lens against bacteria, yeast and mold.
- The finished product is effectively preserved by FDA standards.
- Finished product conforms to USP sterility requirements.

Preclinical

Preclinical toxicology tests have been conducted to substantiate the safety of the product for use in cleaning, rinsing, chemical disinfection, and overnight storage of all soft (hydrophilic) contact lens (Group I, II, III, and IV). The studies include: (1) acute oral toxicity; (2) cytoxicity (agar overlay); (3) mutagenicity (Ames test); (4) sensitization/allergic potential (guinea pig maximization test); (5) ophthalmic container safety; and (6) ocular safety (irritation) evaluations.

Alcon Multi-Purpose Disinfecting Solution ID 90746 should not present an ocular hazard to the consumer when used under the recommended treatment regimens for soft (hydrophilic) contact lenses.

Compatibility/Cleaning Efficacy

Studies were conducted to determine product compatibility with soft contact lenses and its ability to clean laboratory deposited lenses. The studies demonstrated the compatibility and cleaning efficacy of Alcon Multi-Purpose Disinfecting Solution ID 90746.

B. Clinical

A study was conducted to clinically evaluate the safety and efficacy of Alcon Multi-Purpose Disinfecting Solution ID 90746 for cleaning, rinsing, disinfection and storage of all soft (hydrophilic) contact lenses (249 patients/498 eyes - 3 months) (121 patients/242 eyes - extending to 6 months). This clinical study demonstrated the safety and efficacy of Alcon Multi-Purpose Disinfecting Solution ID 90746.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 2 1997

Mr. Michael E. Pfleger
Associate Director, Regulatory Affairs
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K973332
Trade Name: Alcon Multi-Purpose Disinfecting Solution ID 90746
Regulatory Class: II
Product Code: 86 LPN
Dated: August 29, 1997
Received: September 4, 1997

Dear Mr. Pfleger:

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): unknown K973332

Device Name: Alcon Multi-Purpose Disinfecting Solution ID 90746

Indications for Use:

For the daily cleaning, rinsing, disinfecting, and storing of soft (hydrophilic) contact lenses as recommended by your eye care practitioner. For use in chemical (not heat) disinfection.

Alcon Multi-Purpose Disinfecting Solution ID 90746 can also be used as a diluent for OPTI-ZYME® Enzymatic Cleaner.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Myra Smith

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K973332

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