

JAN 14 1999

510(K) SUMMARY

K984575

**Submitted by:**

Ralph H. Larsen  
Manager, Regulatory Affairs  
Alcon Laboratories, Inc.  
6201 South Freeway  
Fort Worth, Texas 76134-2099  
(817) 551-4702 (Phone)  
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**Device Name:**

Common Name: Contact Lens Care Multi-Purpose Solution

Proprietary Name: Multi-Purpose Disinfecting Solution ID 90746  
(Minor specification modification)

**Indications for Use:**

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

For use as a diluent for OPTI-FREE<sup>®</sup> SUPRACLENS<sup>®</sup> Daily Protein Remover.

Multi-Purpose Disinfecting Solution ID 90746 can also be used to dissolve OPTI-ZYME<sup>®</sup> Enzymatic Cleaner

**Description:**

Multi-Purpose Disinfecting Solution ID 90746 is a sterile, buffered, isotonic, aqueous solution containing sodium citrate, sodium chloride, boric acid, sorbitol, AMP-95, TETRONIC<sup>®</sup> 1304, with edetate disodium 0.05%, POLYQUAD<sup>®</sup> (polyquaternium-1) 0.001% and AL-6289 0.0005% as preservatives.

**Substantial Equivalence:**

Multi-Purpose Disinfecting Solution ID 90746 (minor specification modification) is substantially equivalent, in terms of its actions and indications for use, to Multi-Purpose Disinfecting Solution ID 90746 (K973332). Multi-Purpose Disinfecting Solution

ID 90746 (minor specification modification) 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:**

The risk analysis method used to assess the impact of the minor specification modification was prEN 1441, Risk Assessment of Medical Devices. Also an eight day ocular irritation evaluation of the formulation with the minor specification modification was conducted with soft contact lenses in rabbits. Based on the results of this study, Multi-Purpose Disinfecting Solution ID 90746 (minor specification modification) should not present an ocular hazard to the consumer under normal use conditions. Multi-Purpose Disinfecting Solution ID 90746 (minor specification modification) 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.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Ralph H. Larsen  
Manager, Regulatory Affairs  
Alcon Laboratories, Inc.  
6201 South Freeway  
Fort Worth, Texas 76134-2099

Re: K984575  
Trade Name: Multi-Purpose Disinfecting Solution ID 90746  
Product Code: 86 LPN  
Dated: December 22, 1998  
Received: December 23, 1998

Dear Mr. Larsen:

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 (Pre-market 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.

Mr. Ralph H. Larsen - Page 2

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): \_\_\_\_\_

Device Name: Multi-Purpose Disinfecting Solution ID 90746

**Indications for Use:**

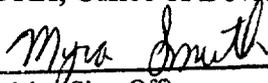
For use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

For use as a diluent for OPTI-FREE® SUPRACLENS® Daily Protein Remover.

Multi-Purpose Disinfecting Solution ID 90746 can be used to dissolve 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)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K984575



Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X