

JUL 24 1998

K981561

April 30, 1998

**Alcon**  
LABORATORIES

**510(K) SUMMARY**

ALCON LABORATORIES, INC.  
6201 SOUTH FREEWAY  
FORT WORTH, TEXAS 76134-2099  
(817) 293-0450

Submitted by:

Ralph H. Larsen  
Manager, Regulatory Affairs  
Alcon Laboratories, Inc.  
6201 South Freeway  
Fort Worth, Texas 76134-2099  
(817) 551-4702 (Phone)  
(817) 551-4630 (Fax)

**Device Name:**

Common Name: Contact Lens Cleaning Solution

Proprietary Name: Liquid Enzyme ID 90133

**Indications for Use:**

Liquid Enzyme ID 90133

Liquid Enzyme ID 90133 is indicated for use with daily wear and extended wear soft (hydrophilic) contact lens to simultaneously enzymatically clean them while they are being disinfected (soaked) in, OPTI-FREE® Rinsing, Disinfecting and Storage Solution, or OPTI-FREE® EXPRESS® Multi-Purpose Solution. **Use as recommended by your eye care practitioner.**

OPTI-FREE® EXPRESS® Multi-Purpose Solution

OPTI-FREE® EXPRESS® Multi-Purpose Solution is for use in chemical (not heat) disinfection and for cleaning, rinsing, disinfecting and storing of clear and tinted, daily and extended wear soft (hydrophilic) contact lenses.

OPTI-FREE® EXPRESS® Multi-Purpose Solution can also be used as a diluent for Liquid Enzyme ID 90133.

OPTI-FREE® Rinsing, Disinfecting and Storage Solution

OPTI-FREE® Rinsing, Disinfecting and Storage Solution is for use in chemical (not heat) disinfection and for rinsing, disinfecting and storing of clear and tinted, daily and extended wear soft (hydrophilic) contact lenses.

OPTI-FREE® Rinsing, Disinfecting and Storage Solution can also be used as a diluent for Liquid Enzyme ID 90133.

**Description:**

Liquid Enzyme ID 90133 is a sterile, trypsin-based enzymatic cleaner buffered with sodium borate. The liquid enzymatic cleaner is formulated for one drop to be diluted in 5 mL of OPTI-FREE® or OPTI-FREE® EXPRESS® Multi-Purpose Solution. Also, this submission provides for labeling changes for OPTI-FREE® EXPRESS® Multi-Purpose Solution and OPTI-FREE® Rinsing, Disinfecting and Storage Solution to be used as diluents for Liquid Enzyme ID 90133.

**Substantial Equivalence:**

This product is substantially equivalent, in terms of its actions and indications for use, to Alcon OPTI-FREE® SUPRACLENS® Daily Protein Remover (PMA 820001/S18), OPTI-FREE® EXPRESS® (PMA 830034/S27) and OPTI-FREE® Rinsing, Disinfection and Storage Solution. (PMA 830034/S03). Liquid Enzyme ID 90133 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 combination Liquid Enzyme ID 90133 in OPTI-FREE® Rinsing, Disinfecting and Storage Solution was evaluated for disinfection efficacy using the FDA guidelines for contact lens solutions. The results demonstrate that the antimicrobial activity of OPTI-FREE® Rinsing, Disinfecting and Storage Solution is not reduced by the addition of Liquid Enzyme ID 90133 against bacteria or fungi.

Preclinical

Comprehensive preclinical toxicology tests have been conducted to evaluate the acute toxicity, ocular toxicity and irritation potential of Liquid Enzyme ID 90133 in conjunction with OPTI-FREE® Rinsing, Disinfecting and Storage Solution. Based on the result of these studies, Liquid Enzyme ID 90133 is safe for its intended use with OPTI-FREE® Rinsing, Disinfecting and Storage Solution in the simultaneous cleaning and disinfection of soft (hydrophilic) contact lenses (Groups I-IV) and should not present an ocular hazard to the consumer under the recommended lens treatment regimen or under conditions of accidental or intentional misuse.

### 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 the Liquid Enzyme ID 90133/OPTI-FREE® *EXPRESS*® Multi-Purpose Solution regimen.

### **B. Clinical**

A study was conducted to clinically evaluate the safety and efficacy of Liquid Enzyme ID 90133/OPTI-FREE® *EXPRESS*® Multi-Purpose Solution regimen for cleaning, rinsing, and disinfection of all soft (hydrophilic) contact lenses (100 patients/200 eyes - 3 months). This clinical study demonstrated the Liquid Enzyme ID 90133/OPTI-FREE® *EXPRESS*® Multi-Purpose Solution regimen is safe and effective for the daily simultaneous enzymatic cleaning and disinfection of soft (hydrophilic) contact lenses.



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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: K981561

Trade Name: Liquid Enzyme ID 90133, OPTI-FREE<sup>®</sup> EXPRESS<sup>®</sup> Multi-Purpose Solution,  
and OPTI-FREE<sup>®</sup> Rinsing, Disinfecting and Storage Solution

Regulatory Class: II

Product Code: 86 LPN

Dated: April 30, 1998

Received: May 1, 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 (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): K981561

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OPTI-FREE® Rinsing, Disinfecting and Storage Solution

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OPTI-FREE® Rinsing, Disinfecting and Storage Solution can also be used as a diluent for Liquid Enzyme ID 90133.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, Ph.D.  
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K981561

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

OR

Over-The-Counter Use X