K981574

JUL 6 1998

510(K) SUMMARY

Submitted by:

Michael E. Pfleger
Director, 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: Soft (hydrophilic) Contact Lens Care Solution

Proprietary Name: OPTI-FREE® *Express*® Multi-Purpose Solution

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.

OPTI-FREE® *Express*® Multi-Purpose Solution can be used to dissolve OPTI-FREE® and OPTI-ZYME® Enzymatic Cleaning Tablets.

Description:

OPTI-FREE® *Express*® Multi-Purpose Solution is a sterile, buffered, isotonic, aqueous solution containing sodium citrate and sodium chloride, with edetate disodium 0.05% and POLYQUAD® (polyquaternium-1) 0.001% as preservatives.

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Substantial Equivalence:

OPTI-FREE® *Express*® Multi-Purpose Solution is substantially equivalent, in terms of its actions and indications for use, to Bausch & Lomb ReNu MultiPlus™ Multi-Purpose Solution cleared for marketing under PMA P860023/S12 and 510(k) K974723. OPTI-FREE® *Express*® Multi-Purpose Solution 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 series of studies were conducted to demonstrate the ability of citrate in OPTI-FREE® Express® Multi-Purpose Solution to continue to remove protein from lenses while they are being stored. Laboratory deposited and human worn lenses were divided and soaked in OPTI-FREE® *Express*® Multi-Purpose Solution and ReNu MultiPlus Multi-Purpose Solution.

These studies demonstrate that OPTI-FREE® *Express*® Multi-Purpose Solution continues to remove protein while lenses are stored and that significantly more protein is removed during soaking in OPTI-FREE® *Express*® Multi-Purpose Solution than in ReNu MultiPlus Multi-Purpose Solution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K981574
Trade Name: OPTI- FREE ® Express ® Multi- Purpose Solution
Regulatory Class: II
Product Code: 86 LPN
Dated: April 30, 1998
Received: May 4, 1998

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):_____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K 981574