

SEP 16 1999

510(K) SUMMARY

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 Care Rewetting Solution

Proprietary Name: OPTI-FREE® *EXPRESS*® Lens Drops

Indications for Use:

OPTI-FREE® *EXPRESS*® LENS DROPS may be used to lubricate and rewet daily, extended wear and disposable soft (hydrophilic) contact lenses as follows:

- Moistening lenses as needed during the day to reduce discomfort.
- Moistening extended wear lenses prior to retiring at night and upon awakening.

Description:

OPTI-FREE *EXPRESS* Lens Drops is a sterile, buffered, isotonic, aqueous solution that contains a citrate buffer and sodium chloride with edetate disodium 0.05% and Polyquad® (polyquaternium-1) 0.001% as preservatives and Clens® – 100.

Substantial Equivalence:

OPTI-FREE *EXPRESS* Lens Drops is substantially equivalent, in terms of its actions and indications for use, to OPTI-FREE Rewetting Drops approved under PMA 830034/S16. OPTI-FREE *EXPRESS* Lens Drops 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

OPTI-FREE *EXPRESS* Lens Drops was evaluated for microbiological safety and effectiveness using the FDA guidelines for contact lens solutions. Results of all tests were in compliance with the FDA testing guidelines

OPTI-FREE *EXPRESS* Lens Drops has been shown to be safe in comprehensive toxicology studies. OPTI-FREE *EXPRESS* Lens Drops should not present a hazard to the consumer when used under the recommended treatment regimen for soft (hydrophilic) contact lenses, or under conditions of accidental or intentional misuse.

B. Clinical

Studies were conducted to clinically evaluate the safety and efficacy of OPTI-FREE *EXPRESS* Lens Drops. These clinical studies demonstrate that OPTI-FREE *EXPRESS* Lens Drops is safe and effective and also significantly reduce lens lysozyme levels on soft contact lenses when used as indicated.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 1999

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

Re: K984573
Trade Name: OPTI-FREE® EXPRESS® Lens Drops
Regulatory Class: II
Product Code: 86 LPN
Dated: July 14, 1999
Received: July 15, 1999

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.

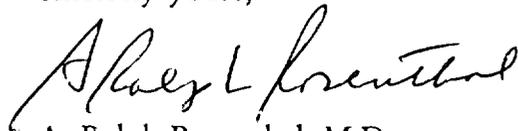
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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 at (301) 443-6597.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "A. Ralph Rosenthal".

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): K984573

Device Name: OPTI-FREE® EXPRESS® Lens Drops

Indications for Use:

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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)



(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K 984573



Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the-Counter Use X