AUG 0 8 2002

K021143

510(K) SUMMARY

Submitted by:

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Device Name:

Common Name: Contact Lens Care Multi-Purpose Disinfecting Solution

Proprietary Name: OPTI-FREE® *EXPRESS*® Multi-Purpose Disinfecting 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 (including silicone hydrogel lenses) as recommended by your eye care practitioner.

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution can also be used as a diluent for OPTI-FREE® SUPRACLENS® Daily Protein Remover.

Description:

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution 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) 0.001% and ALDOX™ (myristamidopropyl dimethylamine) 0.0005% as preservatives.

Substantial Equivalence:

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution is substantially equivalent, in terms of its actions and indications for use, to OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution, cleared for marketing under 510(k) K973332 (originally submitted as P830034/S32), K974624, K983780, K001214 (no rub directions for use for lenses replaced within 30 days or less) and K002589 (no rub directions for all lenses). OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting 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:

Cleaning Studies

A study demonstrated the ability of the product to clean lenses during soaking. The study was done to demonstrate the contribution of the rinse vs. soaking steps to the levels of lysozyme. Elimination of the post-disinfection rinse showed minimal effect on the total amount of lysozyme removed on group IV lenses. This study demonstrates the superiority of OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution over Bausch & Lomb's ReNu Multi-Plus® Multi-Purpose Solution in removing protein from lenses.

Microbiology Studies

A study was conducted to evaluate the performance of OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution in a regimen consisting of a 5 second rinse of lenses per side and soaking the lenses for 6 hours. No rubbing step or final rinse step was used. The results show that OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution evaluated by the test regimen (i.e., lenses rinsed for 5 seconds per lens surface and soaking for 6 hours) meets the FDA guidelines and the ISO 14729:2001 Regimen Test Requirements.

Stand Alone Test:

The antimicrobial activity of OPTI-FREE *Express* FID 90746 was previously evaluated by the ISO 14729 (FDA 510[k]) Stand Alone Test procedure for disinfection of contact lenses (K001214). The results showed that OPTI-FREE *Express* FID 90746 (no soil) met the primary criteria of the Stand Alone Test. The results also showed that organic soil has no deleterious effect on the antimicrobial activity of OPTI-FREE *Express* FID 90746 (K001214).

Regimen Test:

Previously, No Rub™ OPTI-FREE *Express*® was tested and passed the ISO 14729 (FDA 510 [k]) Regimen Test using the approved labeling (i.e., five second rinse per lens surface, six hour soak, and five second rinse per lens surface [no rubbing step]) (K001214). In a new study, OPTI-FREE *Express* FID 90746 was tested by the Regimen Test using a similar regimen, but with less rinsing of the lens (five second rinse per lens surface and six hour soak [no rubbing and no final rinse steps]).

The OPTI-FREE *Express* FID 90746 Investigational Regimen met the criteria of the ISO 14729 (FDA 510[k]) Regimen Test.

It was concluded that the OPTI-FREE *Express* FID 90746 Investigational Regimen provides effective disinfection of contact lenses based on ISO 14729 and the FDA 510(k) performance criteria for contact lens disinfectants.

Clinical Study

A 30-day, randomized concurrently controlled, observer-masked (investigator and chemical analyst) and patient-masked, parallel group, multi-site study was conducted to demonstrate the safety and efficacy of OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution. OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution was used with the modified directions for use. The control used in the study was Bausch & Lomb ReNu Multi-Plus® Multi-Purpose Solution.

This study demonstrated the safety and efficacy of OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution with a rinse/soak regimen.

Significantly less residual lysozyme was found on Group IV lenses from subjects in the OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution regimen compared to lenses from subjects in the ReNu Multi-Plus® Multi-Purpose Solution group on Day 30.

Biocompatibility Testing

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting 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.

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution remains unchanged from the previously approved product (P830034/S32, K973332) except for the labeling change revising the directions for use. The labeling changes require no new biocompatibility testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 8 2002

Alcon Research, LTD
c/o Ralph H. Larsen
Sr. Manager, Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K021143
Trade/Device Name: OPTI-FREE^{R} EXPRESS^{R} Multipurpose Disinfecting Solution
(Modifed Directions for Use)
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: 86 LPN
Dated: June 18, 2002
Received: June 20, 2002

Dear Mr. Larsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K021143

Device Name: OPTI-FREE® *EXPRESS*® Multi-Purpose Disinfecting Solution

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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)

Myra Smith

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises
510(k) Number K021143

Prescription Use_____ OR Over-The Counter Use X

(Per 21 CFR 801.109)