

MAY 10 1999

May 3, 1999

K 990480

Alcon
LABORATORIES

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 Cleaning Solution

Proprietary Name: OPTI-FREE[®] SUPRACLENS[®] Daily Protein Remover

Indications for Use:

OPTI-FREE[®] SUPRACLENS[®] Daily Protein Remover is indicated for use with daily wear and extended wear soft (hydrophilic) contact lens or rigid gas permeable (silicone acrylate and fluorosilicone acrylate) lenses to simultaneously enzymatically clean them while they are being disinfected (soaked) in OPTI-FREE[®] EXPRESS Multi-Purpose Solution, OPTI-FREE[®] Rinsing, Disinfecting and Storage Solution, OPTI-ONE[®] Multi-Purpose Solution, Bausch & Lomb ReNu[®] Multi-Purpose Solution or conditioned in OPTI-SOAK[®] Conditioning Solution. Use as recommended by your eye care practitioner.

Description:

OPTI-FREE[®] SUPRACLENS[®] Daily Protein Remover is a preservative-free solution which contains propylene glycol, sodium borate, and highly purified porcine pancreatin enzymes as the active cleaning ingredient.

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, K974625). OPTI-FREE[®] SUPRACLENS[®] Daily Protein Remover 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 OPTI-FREE[®] SUPRACLENS[®] Daily Protein Remover in Bausch & Lomb ReNu[®] Multi-Purpose Solution was evaluated for disinfection efficacy using the FDA guidelines for contact lens solutions. The OPTI-FREE[®] SUPRACLENS[®] Daily Protein Remover in Bausch & Lomb ReNu[®] Multi-Purpose Solution regimen meets the FDA criteria for disinfection of contact lenses.

Preclinical

Since both OPTI-FREE[®] SUPRACLENS[®] Daily Protein Remover and Bausch & Lomb ReNu[®] Multi-Purpose Solution have been shown to be safe in FDA-accepted toxicology studies, the preclinical safety evaluation in this submission focused on the cytotoxicity and ocular safety of the products when used together in a soft contact lens care regimen. The cytotoxicity evaluation demonstrated that OPTI-FREE[®] SUPRACLENS[®] Daily Protein Remover used with ReNu[®] Multi-Purpose Solution is not cytotoxic in the agar overlay assay. The fourteen-day ocular irritation evaluation in rabbits of OPTI-FREE[®] SUPRACLENS[®] Daily Protein Remover when used with ReNu[®] Multi-Purpose Solution for the daily simultaneous cleaning and disinfection of soft contact lenses demonstrated that the ocular effects produced were generally confined to the conjunctiva, minimal in nature and were judged to be of no clinical significance.

Based on the result of these studies, OPTI-FREE[®] SUPRACLENS[®] Daily Protein Remover is safe for its intended use with Bausch & Lomb ReNu[®] Multi-Purpose 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.

Compatibility/Cleaning Efficacy

Product compatibility with soft contact lenses and the product's ability to clean laboratory deposited lens were evaluated. The cleaning study demonstrated the ability of the OPTI-FREE[®] SUPRACLENS[®] Daily Protein Remover/ Bausch & Lomb ReNu[®] Multi-Purpose Solution regimen to satisfactorily clean deposits commonly found on hydrophilic contact lenses. Also, compatibility of the regimen was demonstrated with hydrophilic soft contact lenses (Groups I through IV) when used daily to concurrently clean and disinfect lenses.

B. Clinical

A clinical study was conducted and demonstrated that the OPTI-FREE[®] SUPRACLENS[®] Daily Protein Remover/ Bausch & Lomb ReNu[®] Multi-Purpose Solution regimen is safe and effective for the daily simultaneous enzymatic cleaning and disinfection of soft (hydrophilic) contact lenses. The study was a three-month, open-label, multi-site study with a descriptive control. The descriptive control was OPTI-FREE[®] SUPRACLENS[®] Daily Protein Remover/ OPTI-FREE[®] Rinsing, Disinfection and Storage Solution/OPTI-FREE[®] Daily Cleaner. Patients wearing soft (hydrophilic) contact lenses from lens polymer groups I and IV were enrolled on a daily wearing schedule. There were 62 patients/124 eyes. The OPTI-FREE[®] SUPRACLENS[®] Daily Protein Remover/ Bausch & Lomb ReNu[®] Multi-Purpose Solution regimen provides clinically equivalent cleaning compared to the historical control regimen in maintaining clinically clean (i.e., visibly clean) lenses. The OPTI-FREE[®] SUPRACLENS[®] Daily Protein Remover/ Bausch & Lomb ReNu[®] Multi-Purpose Solution regimen is clinically acceptable as measured by all efficacy variables including: lens replacements, patient convenience and comfort, corrected visual acuity and lens wearing time. No serious adverse events related or unrelated to the regimen were reported. The incidence of intolerance to the regimen (3.2%) was clinically equivalent to the incidence of intolerance associated with the historical control regimen (2.0%).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 1999

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

Re: K990480
Trade Name: OPTI-FREE® SURPRACLENS® Daily Protein Remover
(For use of Bausch & Lomb ReNu® Multi-Purpose Solution as a diluent,
indicated for simultaneous enzymatic cleaning and disinfection)

Regulatory Class: II
Product Code: 86 LPN
Dated: February 12, 1999
Received: February 16, 1999

Dear Mr. Larsen:

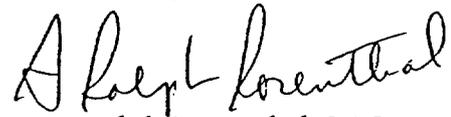
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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.

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: OPTI-FREE® SUPRACLENS® Daily Protein Remover

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)

I. L. B.
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K990480



Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X