K042562

JUL 2 9 2005

510(k) SUMMARY

Lens Plus® Rewetting Drops

This summary uses the format provided in 21 CFR 807.92:

(a)(1) **Submitter:**

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Advanced Medical Optics
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Summary Prepared: July 19, 2005

(a)(2) **Device Trade Name:** Lens Plus® Rewetting Drops
Device Common Name: Soft (Hydrophilic) Contact Lens Solution
Device Classification/Panel: Class II (Special Controls)/Ophthalmic Device
Device Classification Names: Accessories to Contact Lens Solution (86LPN)

(a)(3) **Identification of Predicate Device:** When used as directed, Lens Plus® Rewetting Drops with the sterile daily-use (12 hours) vial is substantially equivalent to the currently-marketed Lens Plus® Rewetting Drops with the single-use vial.

(a)(4) **Device Description:** Lens Plus® Rewetting Drops is a sterile, preservative free, buffered, isotonic, aqueous solution containing sodium chloride and boric acid. The product is packaged in a plastic sterile reclosable vial which allows remaining drops can be used throughout the day (12 hours).

(a)(5) **Intended Use (Indications for Use):** Use LENS PLUS® Rewetting Drops while wearing your lenses to moisten and rehydrate them. Also, use LENS PLUS® Rewetting Drops to relieve minor irritation, discomfort and/or blurring which may occur while wearing your lenses.

(a)(6) **Comparison of Technological Characteristics:** The technological characteristics of the product remain the same.

(b)(1) **Discussion of Nonclinical:**

A bacteriostasis study was conducted in accordance with Micro Appendix C of the Premarket Notification (510(K)) Guidance Document for contact Lens Care Products. The purpose of the study is to evaluate the ability of bacteria to survive in the reclosable vials containing Lens Plus® Rewetting Drops (unpreserved borate buffered saline). A neutralizer efficacy test was also performed to determine the most effective neutralizer recovery medium for the bacteriostasis testing. The results show that *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Candida albicans* and *Aspergillus niger* have no significant growth and survive over the designed period. The data support the desired discard statement on label of up to 12 hours.

(b)(2) **Conclusions Drawn from Data Supporting Equivalence Determination**:

The safety and performance of Lens Plus® Rewetting Drops packaged in a sterile daily-use (12 hours) vial is substantially equivalent to the Lens Plus® Rewetting Drops packaged in the single-use vial currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2005

Advanced Medical Optics, Inc.
c/o Mr. Peter Xu
Regulatory Affairs Professional
1700 E. St. Andrew Place
Santa Ana, CA 92799-5162

Re: K042562
Trade/Device Name: Lens Plus Rewetting Drops
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN
Dated: June 9, 2005
Received: June 13, 2005

Dear Mr. Xu:

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), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042562

Device Name: LENS PLUS® Rewetting Drops

Indications For Use:

Use LENS PLUS® Rewetting Drops while wearing your lenses to moisten and rehydrate them. Also, use LENS PLUS® Rewetting Drops to relieve minor irritation, discomfort and/or blurring which may occur while wearing your lenses.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 K042562