K973921
JAN. 12, 1998

510 (k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

FOR

BAUSCH & LOMB[R] SENSITIVE EYES[R] MULTI-PURPOSE SOLUTION

1. Submitter Information:

Bausch & Lomb Incorporated
Global Vision Care
1400 North Goodman Street
Rochester, New York 14692-0450

Contact Person: Paul Stapleton
Director, Regulatory Affairs

Telephone Number: (716)338-8172

2. Device Name:

Classification Name: Soft (hydrophilic) Contact Lens Solution

Proprietary Name: BAUSCH & LOMB Sensitive Eyes Multi-Purpose Solution

3. Predicate Device:

BAUSCH & LOMB ReNu[R] Multi-Purpose Solution has been selected as the predicate device for BAUSCH & Lomb Sensitive Eyes Multi-Purpose Solution.

4. Description of the Device

BAUSCH & LOMB Sensitive Eyes Multi-Purpose Solution is a multi-purpose solution used in the care of soft (hydrophilic) contact lenses and is indicated for the cleaning, rinsing, disinfection and storage of soft (hydrophilic) contact lenses. It may also be used as a diluent for all BAUSCH & LOMB enzymatic cleaning tablets. The solution is contained in a plastic bottle and consists of a sterile isotonic solution that contains boric acid, edetate disodium, poloxamine, sodium borate and sodium chloride; it is preserved with **[Trademark]** (alexidine dihydrochloride 4 ppm).

Each plastic bottle is supplied sterile and is labeled with a lot number and expiration date.

5. Indications for Use:

BAUSCH & LOMB Sensitive Eyes Multi-Purpose Solution is indicated for use in the daily cleaning, dissolving of Sensitive Eyes Enzymatic Cleaner, ReNu 1-Step or ReNu Effervescent Enzymatic Contact Lens Cleaning Tablets, rinsing and storage of daily and extended wear soft (hydrophilic) contact lenses and chemical (not heat) disinfection, as recommended by your eye care practitioner.

6. Description of Safety and Substantial Equivalence

A series of preclinical and clinical testing was performed to demonstrate the safety and effectiveness of BAUSCH & LOMB Sensitive Eyes Multi-Purpose Solution. A summary of these results from the preclinical and clinical studies is presented below.

Preclinical Testing

A series of *in-vitro* and *in-vivo* preclinical chemical, toxicological and microbiological studies were performed to assess the safety and effectiveness of the product in conformance to the FDA documents entitled **Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products,** April 1, 1995 (DRAFT) and May 1, 1997.

The results of these studies indicate that the physical, chemical and microbiological properties of the BAUSCH & LOMB Sensitive Eyes Multi-Purpose Solution are equivalent to BAUSCH & LOMB ReNu Multi-Purpose Solution.

The solution is not toxic and extracts of lenses treated with the solution are not toxic when tested in laboratory animals.

Clinical Testing

A three (3) month randomized, parallel, double-masked, controlled clinical study was designed in accordance with the **Premarket Notification (510(k)) Guidance for Contact Lens Care Products** of April 1, 1995. The Test Solution was BAUSCH & LOMB Sensitive Eyes Multi-Purpose Solution; the Control Solution was the predicate device, BAUSCH & LOMB ReNu Multi-Purpose Solution. The daily regimen for both solutions consisted of the standard daily rub, rinse and a four (4) hour disinfection procedures. A weekly enzymatic cleaning with ReNu 1-Step Enzymatic Cleaner Tablets occurred.

A total of 154 subjects were enrolled; of these, 102 were enrolled in the Test group and 52 in the Control group. There were 98 completed subjects in the Test group and 51 completed subjects in the Control group. There were seven (7) Investigators.

Analysis of all data from this study showed no clinically significant differences between the Test and Control Groups for clinical findings, visual acuity, lens replacement, lens deposits, discontinued subjects and lens wearing times for the Test and Control groups.

This study has demonstrated the equivalence between BAUSCH & LOMB Sensitive Eyes Multi-Purpose Solution and BAUSCH & LOMB ReNu Multi-Purpose Solution for the care of soft (hydrophilic) contact lenses.

Substantial Equivalence

BAUSCH & LOMB Sensitive Eyes Multi-Purpose Solution is substantially equivalent to BAUSCH & LOMB ReNu Multi-Purpose Solution in that both solutions are formulated similarly with the same indications, usage and clinical experience. They differ in the preservative used in the formulation of the final product; all other aspects of manufacturing are the same. Any differences between the two products, i.e., BAUSCH & LOMB Sensitive Eyes Multi-Purpose Solution and the predicate device do not affect the use of the product.

This product will be sold in plastic bottles as a sterile solution; each bottle will be marked STERILE and will be identified with a Lot Number and Expiration Date.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 1998

Mr. Paul G. Stapleton
Director, Regulatory Affairs
Bausch & Lomb Incorporated
Global Vision Care Division
1400 North Goodman Street
Rochester, NY 14603-0450

Re: K973921
Trade Name: BAUSCH & LOMB Sensitive Eyes Multi-Purpose Solution (preserved with alexidine dihydrochloride)
Regulatory Class: II
Product Code: 86 LPN
Dated: October 14, 1997
Received: October 15, 1997

Dear Mr. Stapleton:

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): K973921

Device Name: Sensitive Eyes® Multi-Purpose Solution

Indications For Use:

Bausch & Lomb Sensitive Eyes Multi-Purpose Solution is indicated for use in the daily cleaning, dissolving of enzymatic cleaning tablets, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care provider.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W.C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K973921

1/9/98

Prescription Use ____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)