K980133

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

MAR 11 1998

FOR

BAUSCH & LOMB® WETTING AND SOAKING SOLUTION

1. SUBMITTER INFORMATION:

Polymer Technology,
a division of Wilmington Partners, L.P.
Global Vision Care
1400 N. Goodman Street
Rochester, New York 14692-0450

2. CONTACT PERSON:

Debra Ketchum
Manager, Regulatory Affairs
Address: 1400 North Goodman Street
Rochester, New York 14692
Telephone No.: (716) 338-8638
Fax No.: (716) 338-0702
E-mail Address: dketchum@bausch.com

3. DEVICE IDENTIFICATION:

Classification Name: Rigid Gas Permeable Contact Lens Solution
Proprietary Name: BAUSCH & LOMB® Wetting and Soaking Solution
Common Name: Contact Lens Conditioning Solution

4. PREDICATE DEVICE:

BAUSCH & LOMB Wetting and Soaking Solution has been selected as the predicate device for the modified *BAUSCH & LOMB Wetting and Soaking Solution.*

5. DESCRIPTION OF THE DEVICE:

BAUSCH & LOMB Wetting and Soaking Solution is a sterile conditioning solution used in the care of rigid gas permeable and hard (PMMA) contact lenses and is indicated for the disinfecting and soaking after cleaning and rinsing of fluoro silicone acrylate, silicone acrylate and hard (PMMA) contact lenses. This product is contained in a plastic bottle, and consists of a sterile, buffered solution, preserved with chlorhexidine gluconate and edetate disodium.

6. INDICATIONS FOR USE:

BAUSCH & LOMB Wetting and Soaking Solution is indicated for use in the disinfecting and soaking after cleaning and rinsing of fluoro silicone acrylate, silicone acrylate rigid gas permeable and hard (PMMA) contact lenses.

7. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE:

A series of preclinical testing was performed to demonstrate the safety and effectiveness of the modified *BAUSCH & LOMB Wetting and Soaking Solution.* A summary of these results from the preclinical studies is presented below.

Toxicology:

In-Vitro Cytotoxicity:
USP Agar Diffusion Cytotoxicity was completed in accordance with USP XXII. The test article meets the requirements of the Agar Diffusion Test.

Acute Ocular Irritation:
Acute Ocular Irritation test was performed and produced no ocular irritation.

The results of all testing demonstrated that the safety and effectiveness of the modified *BAUSCH & LOMB Wetting and Soaking Solution* is equivalent to the currently marketed BAUSCH & LOMB Wetting and Soaking Solution.

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

Microbiology:

Preservative Effectiveness:
Product stored up to 36 months at room temperature were tested for Preservative Effectiveness. The results of this test demonstrate that the product meets the relevant preservative efficacy requirements.

Disinfection Efficacy:
Product stored at room temperature for 36 months was tested. The results of this evaluation demonstrate that the product meets the ISO Stand Alone Procedure for Disinfecting Products Primary Acceptance Criteria requirements.

Shelf Life:
Expiration dating was established based on 36 months room temperature data.

Solution Compatibility:
BOSTON IV (silicone acrylate), BOSTON ES (fluoro silicone acrylate) tinted rigid gas permeable contact lenses and BP Flex PMMA contact lenses were subjected to a thirty cycle lens compatibility study with the modified *BAUSCH & LOMB Wetting and Soaking Solution* and BAUSCH & LOMB Concentrated Cleaner.

After thirty repeated cycles with BAUSCH & LOMB Concentrated Cleaner and the modified *BAUSCH & LOMB Wetting and Soaking Solution*, all of the physical and lens parameters tested for BOSTON IV, BOSTON ES rigid gas permeable and BP FLEX hard tinted contact lenses were within ISO specifications for rigid corneal and scleral contact lenses. There were no change in the cosmetic appearance.

Wetting Angle:

This study investigated retention of the modified *BAUSCH & LOMB Wetting and Soaking Solution* and the currently marketed BAUSCH & LOMB Wetting and Soaking Solution on three selected RGP lens materials, BOSTON IV (silicone acrylate), BOSTON ES (fluoro silicone acrylate) tinted rigid gas permeable contact lenses and BP Flex PMMA contact lenses. Dynamic contact angle (DCA) analysis was the method chosen to measure the desorption of solution from the lens material surface. The results of the DCA testing indicate that the modified *BAUSCH & LOMB Wetting and Soaking Solution* and the currently marketed BAUSCH & LOMB Wetting and Soaking Solution are equivalent in their behavior.

8. SUBSTANTIAL EQUIVALENCE

The modified *BAUSCH & LOMB Wetting and Soaking Solution* is substantially equivalent to the currently marketed BAUSCH & LOMB Wetting and Soaking Solution, approved July 11, 1984 under PMA P820070, Supplement 2, in that both products are formulated similarly, with the same indications, usage, and all aspects of manufacturing. The two products differ only in that one of the tonicity agents in the modified *BAUSCH & LOMB Wetting and Soaking Solution* has a lower concentration than found in the currently marketed 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

MAR 11 1998

Ms. Debra L.B. Ketchum
Manager, Regulatory Affairs
Polymer Technology
1400 N. Goodman Street
Rochester, NY 14692

Re: K980133
Trade Name: BAUSCH & LOMB® Wetting and Soaking Solution
Regulatory Class: II
Product Code: 86 LPN
Dated: January 14, 1998
Received: January 15, 1998

Dear Ms. Ketchum:

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 at (301) 443-6597.

Sincerely yours,

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

Enclosure

Polymer Technology,
a division of Wilmington Partners, L.P.
1400 North Goodman Street
Rochester, NY 14692-0450

Indications for Use Statement

510(k) Number (if known): K980133

Device Name: BAUSCH & LOMB® Wetting and Soaking Solution

Indications for Use:

BAUSCH & LOMB® Wetting and Soaking Solution is indicated for use in disinfecting and soaking after cleaning and rinsing of fluoro silicone acrylate, silicone acrylate rigid gas permeable and hard (PMMA) contact lenses.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use ✓

Daniel W. C. Brown, PH.D.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980133