

NOV 3 1998

K982775

**510 (k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS**

FOR

**BAUSCH AND LOMB ReNu [TBD]
MULTI-PURPOSE SOLUTION**

1. Submitter Information

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

Contact Person: Paul G. Stapleton
Director, Global Regulatory Affairs

Telephone Number: 716-338-8172

2. Device Name

Classification Name: Soft (hydrophilic) Contact Lens Solution

Proprietary Name: BAUSCH & LOMB ReNu [TBD] Multi-Purpose Solution

3. Predicate Device

Bausch & Lomb Sensitive Eyes Multi-Purpose Solution cleared under K 973921 has been selected as the predicate device for Bausch & Lomb ReNu [TBD] Multi-Purpose Solution with the new indication of 10 minute disinfection cycle.

4. Description of the Device

BAUSCH & LOMB ReNu [TBD] 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 enzymatic cleaning tablets which are to be used in conformance to the established labeling directions of the 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 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 ReNu [TBD] Multi-Purpose Solution is indicated for use in the daily cleaning, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care provider. It is also indicated for use in dissolving enzymatic cleaning tablets.

6. Description of Safety and Substantial Equivalence

A series clinical and preclinical, testing was performed to demonstrate the safety and efficacy of Sensitive Eyes Multi-Purpose Solution; all studies had previously been submitted under K 973921 which cleared January 12, 1998. A summary of that testing has been previously provided.

To support a claim of 10 minute disinfection cycle time, a series of microbiological testing has been completed at time period ranging from 10 minutes to 240 minutes. All results were satisfactory.

Substantial Equivalence

BAUSCH & LOMB ReNu [TBD] Multi-Purpose Solution is substantially equivalent to the predicate device. BAUSCH & LOMB ReNu [TBD] Multi-Purpose Solution in a 10 minutes disinfection cycle time is microbiologically equivalent to a 4 hour disinfection cycle time.

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.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K982775
Trade Name: BAUSCH & LOMB® Renu® [TBD™] Multi Purpose Solution
Regulatory Class: II
Product Code: 86 LPN
Dated: August 5, 1998
Received: August 7, 1998

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.

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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

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14692-0450

Indications for Use Statement

510(k) Number (if known): _____

Device Name: BAUSCH & LOMB ReNu [TM TBD] Multi-Purpose Solution

Indications for Use:

BAUSCH & LOMB ReNu [TM TBD] Multi-Purpose Solution is indicated for use in the daily cleaning, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care provider. It is also indicated for use in dissolving enzymatic cleaning tablets.

(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 X

Myna Smith 

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K 982775