JUN 24 1998

K980591

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

BAUSCH & LOMB
ReNu MultiPlus™ Lubricating & Rewetting Drops

1. Submitter Information:

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

Contact Person: Kim S. DeVitto
Manager, Regulatory Affairs

Telephone Number: (716) 338-6401

2. Device Name:

Classification Name: In-Eye Soft (hydrophilic) Contact Lens Solution (Lubricating and/or Rewetting Drops

Proprietary Name: ReNu MultiPlus™ Lubricating & Rewetting Drops

3. Predicate Device:

The Bausch & Lomb products, ReNu Lubricating & Rewetting Drops and Sterile Lens Lubricant were selected as the predicate devices for ReNu MultiPlus™ Lubricating & Rewetting Drops.

4. Description of the Device

Bausch & Lomb ReNu MultiPlus Lubricating & Rewetting Drops is a sterile, buffered, isotonic solution containing the demulcent povidone. The solution is preserved with edetate disodium and sorbic acid, both at a concentration of 0.1%. Boric acid, potassium chloride, sodium borate and sodium chloride act as buffering and tonicity agents. The solution is supplied sterile in a low density polyethylene bottle labeled with a lot number and expiration date.

5. Indications for Use:

Bausch & Lomb ReNu MultiPlus™ Lubricating & Rewetting Drops are indicated for use to lubricate and rewet soft (hydrophilic) contact lenses during wear. The product may be used with daily wear or extended wear lenses and with disposable lenses or lenses prescribed for frequent replacement.

6. Description of Safety and Substantial Equivalence

A series of preclinical tests and clinical testing was performed to demonstrate the safety and effectiveness of ReNu MultiPlus Lubricating & Rewetting Drops. A summary of the test results is provided 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 accordance with the guidelines set forth in FDA's May 1, 1997 **Guidance for Industry - Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products**.

The results of these studies indicate that the physical, chemical and microbiological properties of Bausch & Lomb ReNu MultiPlus Lubricating & Rewetting Drops are substantially equivalent to the predicate devices, Bausch & Lomb ReNu Lubricating & Rewetting Drops and Sterile Lens Lubricant.

The solution is non-toxic to the ocular tissue as demonstrated by *in-vivo* preclinical testing in laboratory animals. *In-vitro* lens compatibility testing was conducted to establish product compatibility with soft (hydrophilic) contact lenses.

Clinical Testing

A one (1) month study was conducted to clinically evaluate the safety and efficacy of Bausch & Lomb ReNu MultiPlus Lubricating & Rewetting Drops for use in the lubricating and rewetting of soft (hydrophilic) contact lenses during wear. The clinical study was designed in accordance with the **Premarket Notification (510 (k)) Guidance for Contact Lens Care Products** of May 1, 1997. The test cell included Bausch & Lomb ReNu MultiPlus™ Lubricating & Rewetting Drops. The control cell consisted of the predicate device, Bausch & Lomb ReNu^{R} Lubricating & Rewetting Drops.

A total of 87 subjects (174 eyes) successfully completed the study, 59 subjects (93.7%) from the Test Group and 28 subjects (90.3%) from the Control Group. During this study, no adverse events were reported; there were not significant differences between Test and Control regimens for slit lamp evaluations or patient symptoms. Significant differences were not seen between the Test and Control Groups with respect to physiological response, visual acuity and average daily wear times.

Results of the clinical study demonstrate the safety, effectiveness and substantial equivalence of Bausch & Lomb ReNu MultiPlus™ Lubricating & Rewetting Drops to the predicate device for lubricating and rewetting soft (hydrophilic) contact lenses.

7. Substantial Equivalence

Bausch & Lomb ReNu MultiPlus Lubricating & Rewetting Drops are substantially equivalent in terms of indications for use, safety and effectiveness to the predicate devices: Bausch & Lomb ReNu Lubricating & Rewetting Drops (approved for marketing under PMA P820031) and Bausch & Lomb Sterile Lens Lubricant (approved for marketing under NDA N17-945). Any differences between the new device and its predicates do not effect the use of this product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 1998

Kim S. DeVitto
Manager, Regulators Affairs
Baush & Lomb Inc.
1400 North Goodman St.
Rochester, NY 14692-0450

Re: K980591
Trade Name: ReNu Multiplus ™ Lubricating & Rewetting Drops
Regulatory Class: II
Product Code: 86 LPN
Dated: May 21, 1998
Received: May 22, 1998

Dear Ms. DeVitto:

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

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K980591**

Device Name: **ReNu MultiPlus™ Lubricating & Rewetting Drops**

Indications for Use:

Bausch & Lomb ReNu MultiPlus™ Lubricating & Rewetting Drops are indicated for use to lubricate and rewet soft (hydrophilic) contact lenses during wear. The product may be used with daily wear or extended wear lenses and with disposable lenses or lenses prescribed for frequent replacement.

(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 X
Use X
(Per 21 CFR 801.109)

Daniel W. C. Brown P.H.D
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980591