3/29

K983225

510 (k) Summary

Of Safety and Effectiveness

Bausch & Lomb ReNu ®Effervescent Enzymatic Contact Lens Cleaner

1. Submitter Information:

Bausch & Lomb Incorporated
Global Vision Care Division
1400 N Goodman Street
Rochester N.Y 14692 - 0450

Contact Person: Yvonne Middlefell
Global Regulatory Affairs Manager

Telephone Number: 716-338- 8460
Fax Number: 716- 338- 0702

2. Device Name:

Classification Name: Soft (Hydrophilic) Contact Lens Periodic Cleaner
Proprietary Name: Bausch & Lomb ReNu® Effervescent Enzymatic Contact Lens Cleaner.

3. Predicate Device:

Bausch & Lomb Sensitive Eyes® Enzymatic Cleaner.

4. Description of Device:

Bausch & Lomb ReNu® Effervescent Enzymatic Contact Lens Cleaner is supplied in a tablet format packaged in a foil strip. The tablets contain a proteolytic enzyme, Subtilisin, Polyethylene Glycol 3350 as a binding agent and salts for effervescence and tonicity. The tablet may be dissolved in either preserved or sterile un-preserved saline solution or Bausch & Lomb ReNu® MultiPurpose Solution.

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Bausch & Lomb ReNu ®Effervescent Enzymatic Contact Lens Cleaner

5. Indications for use:

Bausch & Lomb ReNu® Effervescent Enzymatic Contact Lens Cleaner is indicated for use with either heat or chemical lens care systems in the weekly cleaning of soft contact lenses.

6. Description of Safety and Substantial Equivalence.

A series of non- clinical studies were completed for Bausch & Lomb ReNu® Effervescent Enzymatic Contact Lens Cleaner. These studies evaluated the physical and chemical properties of the product under specified storage conditions. Cleaning Efficacy, Toxicology and Microbiological studies were also performed to demonstrate the safety and effectiveness of the device in conformance with the FDA document entitled **Premarket Notification 510 (k) Guidance Document for Contact Lens Care Products** dated May 1 1997.

The results of these studies indicate that the Physical, Chemical, Microbiological and Toxicological Properties of for Bausch & Lomb ReNu® Effervescent Enzymatic Contact Lens Cleaner are substantially equivalent to the Bausch & Lomb Sensitive Eyes® Enzymatic Cleaner.

7. Clinical Study:

In accordance with the FDA document entitled **Premarket Notification 510 (k) Guidance Document for Contact Lens Care Products**. May 1 1997, Bausch & Lomb made the determination that a clinical study is not required to demonstrate the safety and effectiveness of this device.

The product has the same qualitative formulation and is manufactured following the same process and similar quality standards as the predicate device, Bausch & Lomb Sensitive Eyes® Enzymatic Cleaner.

510 (k) Summary

Of Safety and Effectiveness

Bausch & Lomb ReNu ®Effervescent Enzymatic Contact Lens Cleaner

8. Substantial Equivalence:

The Bausch & Lomb ReNu ® Effervescent Enzymatic Contact Lens Cleaner is substantially equivalent to the Bausch & Lomb Sensitive Eyes® Enzymatic Cleaner.

Both of these products have the same indications for use, the same qualitative formulation and are manufactured following the same process and similar quality standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 29 1999

Yvonne Middlefell
Manager, Global Regulatory Affairs
Bausch & Lomb Incorporated
1400 N Goodman Street
Rochester, NY. 14692-0450

Re: K983225
Trade Name: Bausch & Lomb ReNu ® Effervescent Enzymatic Contact Lens Cleaner
Regulatory Class: II
Product Code: 86 LPN
Dated: February 3, 1999
Received: February 4, 1999

Dear Ms. Middlefell:

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

510k Premarket Notification for Bausch & Lomb ReNu® Effervescent Enzymatic Contact Lens Cleaner

Bausch & Lomb Incorporated
1400 N. Goodman Street
Rochester N.Y. 14692-0450

Indications For Use Statement

510(K) Number (if known): K983225

Device Name: Bausch & Lomb ReNu® Effervescent Enzymatic Contact Lens Cleaner

Indications for Use:

Bausch & Lomb ReNu® Effervescent Enzymatic Contact Lens Cleaner is indicated for use with either heat or chemical lens care systems in the weekly cleaning of soft contact lenses.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ming-Chien Shih JS

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K983225

Prescription Use_____ or Over The Counter- Use ✓