K013232

NOV 2 0 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

CyberCases™
by BAUSCH & LOMB

1. **Submitter Information:**

Bausch & Lomb Incorporated
1400 North Goodman Street
P.O. Box 30450
Rochester, New York 14603-0450

Contact Person: Kim S. DeVitto
Manager, Regulatory Affairs
Telephone No.: 716-338-6401
Fax No.: 716-338-0702

2. **Device Name:**

Classification Name: Contact Lens Cases

Proprietary Name: CyberCases™ by Bausch & Lomb

3. **Predicate Device:**

The Bausch & Lomb® Sight Savers® Contact Lens Case was selected as the predicate device for the CyberCases by Bausch & Lomb.

4. **Description of the Device**

CyberCases by Bausch & Lomb consist of a polypropylene cap and polypropylene body for storage of hard, rigid gas permeable (fluro silicone acrylate and silicone acrylate) and soft (hydrophilic) contact lenses during chemical disinfection.

5. Indications for Use:

CyberCases by Bausch & Lomb are indicated for storage of hard, rigid gas permeable (fluro silicone acrylate and silicone acrylate) and soft (hydrophilic) contact lenses during chemical disinfection.

6. Description of Safety and Substantial Equivalence

A series of *in-vitro* toxicological and chemical studies were performed to assess the safety and effectiveness of the CyberCases by Bausch & Lomb 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.** All studies were conducted in compliance with the Good Laboratory Practice Regulation for Nonclinical Laboratory Studies.

Results of the testing demonstrate that the safety and effectiveness of the CyberCases by Bausch & Lomb is equivalent to the predicate device, Bausch & Lomb Sight Savers Contact Lens Case.

7. Substantial Equivalence

CyberCases by Bausch & Lomb are substantially equivalent in terms of indications for use, safety and effectiveness to the predicate device, Bausch & Lomb Sight Savers Contact Lens Case, cleared for marketing under 510(k) Notification #K852384 on 7/31/1985. The addition of different colorants to the lens case does 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

NOV 2 0 2001

Bausch & Lomb, Inc.
c/o Kim S. DeVitto
Manager, Regulatory Affairs
1400 N Goodman Street
P.O. Box 30450
Rochester, NY 14603

Re: K013232
Trade/Device Name: CyberCases™ by Bausch & Lomb®
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products (contact lens cases)
Regulatory Class: Class II
Product Code: LRX
Dated: September 26, 2001
Received: September 27, 2001

Dear 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 Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

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

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): N/A

Device Name: CyberCases™ by Bausch & Lomb

Indications for Use:

CyberCases by Bausch & Lomb are indicated for use in the storage of hard, rigid gas permeable (fluro silicone acrylate and silicone acrylate) and soft (hydrophilic) contact lenses during chemical disinfection

(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 _____
(Per 21 CFR 801.109)

Daniel W. Brown, Ph.D.
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K013232