K972454

AUG - 8 1997

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

FOR

BAUSCH & LOMB® OxyCor (balafilcon A) Visibility Tinted Contact Lens

1. **Submitter Information:**

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

Contact Person: Dennis Hahn
Manager, Regulatory Affairs
Telephone No.: (716) 338-6813

2. **Device Name:**

Classification Name: Soft (hydrophilic) contact lens

Proprietary Name: BAUSCH & LOMB® OxyCor (balafilcon A) Visibility Tinted Contact Lens

3. **Predicate Device:**

The BAUSCH & LOMB® Premier 90 (balafilcon A) Contact Lens (clear lens) and the BAUSCH & LOMB Optima™ 38 (polymacon) Visibility Tinted Contact Lens have been selected as the predicate devices for the BAUSCH & LOMB® OxyCor (balafilcon A) Visibility Tinted Contact Lens.

4. DESCRIPTION OF DEVICE

The BAUSCH & LOMB® OxyCor (balafilcon A) Visibility Tinted Contact Lens is a hemispherical flexible shell which covers the cornea and may cover a portion of the adjacent sclera. It consists of a copolymer of a silicone vinylcarbamate, N-vinyl pyrrolidinone, a siloxane crosslinker and a vinyl alanine wetting monomer, and is 36% water by weight when immersed in a sterile borate buffered saline solution. The lens is tinted blue with up to 300ppm of the color additive Reactive Blue Dye 246 [(1,4-Bis[4-(2-methacryl oxyethyl) phenylamino] anthraquinone]. The color additive conforms with 21 CFR Part 73.3106.

The physical / optical properties of the lens are:

Specific Gravity:	1.064
Refractive Index:	1.426
Light Transmittance:	C.I.E. Y value - at least 95%
Water Content:	36%
Oxygen Permeability (Dk):	99 x10^{-11}[cm^3O_2(STP) x cm]/(sec x cm^2 x mmHg)@35°C (Polarographic Method)

The BAUSCH & LOMB® OxyCor (balafilcon A) Visibility Tinted Contact Lens is a hemispherical shell of the following dimensions:

- Diameter: 13.5mm to 15.0mm
- Center Thickness: 0.05mm to 0.75mm
- Base Curve: 7.8mm to 9.5mm
- Powers (Spherical): +20.00D to -20.00D
  Toric (Cylinder): 0 to 10 Diopters
  Toric Axis: 0° to 180°

Each BAUSCH & LOMB® OxyCor (balafilcon A) Visibility Tinted Contact Lens is supplied in a glass vial container with a solution of borate buffered saline. The container is marked with the manufacturing lot number of the lens, the base curve, sphere power, diameter and expiration date. In addition to the above, toric lenses are marked with cylinder power and axis information.

5. INDICATIONS FOR USE

The BAUSCH & LOMB® OxyCor (balafilcon A) Visibility Tinted Contact Lens is indicated for vision correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes, that exhibit refractive astigmatism up to 10.00 diopters. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

The lens may be disinfected using either a heat or chemical disinfection system. Eye Care Practitioners may prescribe the lens for traditional or frequent/planned replacement wearing schedule, with cleaning, disinfection and scheduled replacement of the lens.

6. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE

A series of preclinical and clinical testing was performed to demonstrate the safety and effectiveness of the BAUSCH & LOMB® OxyCor (balafilcon A) Contact Lens. A summary of results from the preclinical and clinical tests is provided below.

Preclinical Testing:

A series of *in vitro* and *in vivo* preclinical toxicology and biocompatibility testing was performed to assess the safety and effectiveness of the contact lens device. Testing was performed in accordance with FDA guidelines titled, Guidance document for Class III Contact Lenses, April 1989 and Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses, May 1994. All non-clinical laboratory studies were conducted in compliance with the GLP regulation.

The results of the preclinical testing on the Bausch & Lomb OxyCor (balafilcon A) Visibility Tinted Contact Lens demonstrate that:

The physicochemical properties of the BAUSCH & LOMB® OxyCor (balafilcon A) Visibility Tinted Contact Lens are equivalent to the predicate device, BAUSCH & LOMB® Premier 90 (balafilcon A) Contact Lens (clear lens). Differences in spectral properties of the two devices are due to the addition of the tint. Differences in oxygen permeability are due to process improvements.

The lens material is not toxic and the extracts are not irritating.

The extracts of the lens material do not show any detectable quantities of monomer components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 1997

Mr. Dennis Hahn
Manager, Regulatory Affairs
BAUSCH & LOMB, Inc.
1400 N. Goodman Street
P.O. Box 450
Rochester, NY 14692-0450

Re: K972454
Trade Name: BAUSCH & LOMB®
OxyCor (balafilcon A) Visibility
Tinted Contact Lens for Daily Wear
Regulatory Class: II
Product Code: 86 LPL
Dated: June 27, 1997
Received: July 1, 1997

Dear Mr. Hahn:

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 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): K972454

Device Name: BAUSCH & LOMB® OxyCor (balafilcon A) Visibility Tinted Contact Lens

Indications for Use:

The BAUSCH & LOMB® OxyCor (balafilcon A) Visibility Tinted Contact Lens is indicated for vision correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes, that exhibit refractive astigmatism up to 10.00 diopters. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

The lens may be disinfected using either a heat or chemical disinfection system. Eye Care Practitioners may prescribe the lens for traditional or frequent/planned replacement wearing schedule, with cleaning, disinfection and scheduled replacement of the lens.

Claims:

1. The BAUSCH & LOMB® OxyCor (balafilcon A) Visibility Tinted Contact Lens provides vision correction in powers ranging from +20.00D to -20.00D.

2. The BAUSCH & LOMB® OxyCor (balafilcon A) Visibility Tinted Contact Lens provides vision correction of refractive astigmatism in powers up to 10.00 diopters.

3. The BAUSCH & LOMB® OxyCor (balafilcon A) Visibility Tinted Contact Lens may be disinfected using either a heat or chemical disinfection system.

(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 K972454