

K974780

MAR 11 1998

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

FOR

**BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon 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® SofLens™ one day disposable (hilafilcon A)
Visibility Tinted Contact Lens

3. Predicate Device:

The BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens
has been selected as the predicate devices for the BAUSCH & LOMB® SofLens™ one
day disposable (hilafilcon A) Visibility Tinted Contact Lens.

4. DESCRIPTION OF DEVICE

The BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon 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 2-hydroxyethyl methacrylate and N-vinyl pyrrolidinone, and is 70% water by weight when immersed in a sterile saline solution. This lens is tinted blue with either D&C Green #6 or Reactive Blue Dye 246 ((1,4-Bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone). The color additives conform with 21 CFR Part 74.3206 and 21 CFR Part 73.3106, respectively. The lens may also be supplied clear (no tint).

The physical / optical properties of the lens are:

| | |
|---------------------------|--|
| Specific Gravity: | 1.075 |
| Refractive Index: | 1.38 |
| Light Transmittance: | C.I.E. Y value - at least 97% |
| Water Content: | 70% |
| Oxygen Permeability (Dk): | $33 \times 10^{-11} [\text{cm}^3 \text{O}_2 (\text{STP}) \times \text{cm}] / (\text{sec} \times \text{cm}^2 \times \text{mmHg}) @ 35^\circ \text{C}$ (Polarographic Method) |

The BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon 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

Each BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens is supplied in a plastic blister container with a saline solution. The container is marked with the manufacturing lot number of the lens, the base curve, sphere power, diameter and expiration date.

5. INDICATIONS FOR USE

The BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

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® SofLens™ one day disposable (hilafilcon 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 guideline titled 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® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens demonstrate that:

The physicochemical properties of the BAUSCH & LOMB® SofLens™ (hilafilcon A) one day disposable Visibility Tinted Contact Lens are equivalent to the predicate device, BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens. The slight differences in the water content of the lens materials accounts for the measured variations in the physicochemical properties between the two lens types.

The extracts of the lens material do not show any significant quantities of monomer components and toxicity testing results of lens extracts and lens material demonstrated no toxicity or irritation.

Clinical Testing:

A three month clinical study was completed to demonstrate that the BAUSCH & LOMB® SofLens™ one day disposable (hilaflcon A) Visibility Tinted Contact Lens (Test) is substantially equivalent in safety and efficacy to the currently marketed BAUSCH & LOMB® SofLens66™ (alphaflcon A) Visibility Tinted Contact Lens (Control), when worn by myopic phakic patients on a daily wear basis. The study was carried out in accordance with the Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses, May 1994.

A total of 242 eyes (121 patients) were entered into the study by 10 investigators. This was a randomized three cell study design. Patients in one cell wore a pair of the Test Lenses with daily replacement schedule (58 patients), patients in the second cell wore a pair of the Test Lenses with monthly replacement schedule (29 patients), while patients in the third cell wore a pair of Control Lenses with no scheduled replacement of lenses (30 patients). Prior to entry into the study, each patient was required to read and sign a Statement of Informed Consent. Study lenses could not be placed on a patient's eye until the Statement of Informed Consent had been completed by the patient and Investigator.

The primary endpoints for this study were:

- Safety: A difference of 10% in the proportions of total grade 2 or greater positive slit lamp findings, between the Test and Control lenses was considered significant.
- Efficacy: Test lens is not significantly different from the Control lens is the proportions of lens visual acuities at the level of 20/40 or better.

There were no significant differences seen between either Test lens modalities (daily and monthly replacement schedule) and the Control lens with respect to physiological response as determined by slit lamp examination. Therefore, the Safety endpoint of the study was achieved.

On eye, measured Snellen visual acuity data showed no difference between the Test and Control lenses, attaining the Efficacy endpoint.

Both the safety and efficacy endpoints, as defined in the study protocol, were achieved, and almost all differences between the Test and Control lenses, for other parameters can be attributed to inadequate lens fit, due to a lack of base curve choices with the Test lens. Based on these data, the Sponsor concludes that the Test lens, is substantially equivalent in both safety and efficacy to the Control lens, when used on a daily wear basis, for both daily and monthly replacement schedules.

Substantial Equivalence

The BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens is similar to the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens, in that both fall into the same FDA material classification grouping (Group II) and both are manufactured by the same manufacturing process (cast molding). The BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens is different from the BAUSCH & LOMB® SofLens66™ (alphafilcon A) Visibility Tinted Contact Lens in that it has a different USAN name (hilafilcon A vs. alphafilcon A). The differences between these two lenses will not have any negative effect on the safety and effectiveness of the device.

All product will be sold as sterile medical devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Dennis Hahn
Manager, Regulatory Affairs
Vision Care Division
Bausch & Lomb, Inc.
1400 N. Goodman Street
PO Box 450
Rochester, NY 14603-0450

MAR 11 1998

Re: K974780
Trade Name: Bausch & Lomb SofLens one day disposable (hilafilcon A) Visibility
Tinted (D & C Green #6 and Reactive Blue 246) Contact Lens (cast
moulded) for Daily Wear
Regulatory Class: II
Product Code: 86 LPL
Dated: December 19, 1997
Received: December 22, 1997

Dear Mr. Hahn:

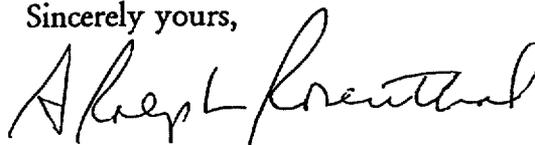
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 at (301) 443-6597.

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): K974780

Device Name: BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A)
Visibility Tinted Contact Lens

Indications for Use:

The BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

Claims:

1. The BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens provides vision correction in powers ranging from +20.00D to -20.00D.
2. The BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens is for single-use disposable wear.

(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

David W. C. Brown, Ph.D.
(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K974780