

MAR - 3 2000

K994125

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

FOR

BAUSCH & LOMB® 2-Week (hilafilcon B) Visibility Tinted Contact Lens

1. Submitter Information:

Bausch & Lomb Incorporated
Global Vision Care Division
1400 North Goodman Street
Rochester, NY 14603-0450

Contact Person: Glenn A. Davies, O.D.
Director, Regulatory Affairs
Telephone No.: (716) 338-8215

2. Device Name:

Classification Name: Soft (hydrophilic) contact lens

Proprietary Name: BAUSCH & LOMB® 2-Week (hilafilcon B) Visibility Tinted
Contact Lens

3. Predicate Devices:

SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens (K974780)

Phoenix (hilafilcon A) Visibility Tinted Contact Lens (K983894)

4. DESCRIPTION OF DEVICE

The BAUSCH & LOMB® 2-Week (hilafilcon B) 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 59% water by weight when immersed in a sterile saline solution. This lens is tinted blue with Reactive Blue Dye 246 ((1,4-Bis[4-(2-methacryloxyethyl) phenylamino] anthraquinone). The color additive conforms with 21 CFR Part 73.3106. The lens may also be supplied clear (no tint).

The physical / optical properties of the lens are:

Specific Gravity:	1.119
Refractive Index:	1.4036
Light Transmittance:	C.I.E. Y value - at least 97%
Water Content:	59%
Oxygen Permeability (Dk):	$22 \times 10^{-11} [\text{cm}^3 \text{O}_2 (\text{STP}) \times \text{cm}] / (\text{sec} \times \text{cm}^2 \times \text{mmHg}) @ 35^\circ \text{C}$ (Polarographic Method)

The BAUSCH & LOMB® 2-Week (hilafilcon B) 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® 2-Week (hilafilcon B) 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® 2-Week (hilafilcon B) Visibility Tinted Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-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.

Replacement schedules may vary from patient to patient, and should be decided by eye care practitioners in consultation with their patients. The lens is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lens may be disinfected using a chemical disinfection system.

6. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE

A series of non-clinical laboratory testing and clinical testing was performed to demonstrate the safety and effectiveness of the BAUSCH & LOMB® 2-Week (hilafilcon B) Contact Lens. A summary of results from the preclinical and clinical tests is provided below.

Non-Clinical Laboratory 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® 2-Week (hilafilcon B) Visibility Tinted Contact Lens demonstrate that:

The hilafilcon B contact lens material is similar to the hilafilcon A contact lens material. The differences between the two lens materials are primarily due to the difference in water content. 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. The lenses are compatible with chemical disinfection systems (including hydrogen peroxide).

Stability testing has demonstrated a three year expiration date for the sterile lenses.

Clinical Testing:

A one month, randomized clinical study was completed to evaluate the safety and efficacy of the Bausch & Lomb 2-Week Contact Lens (Test) compared to the Bausch & Lomb SofLens one day™ Contact Lens (Control) when worn by myopic, phakic patients on a daily wear basis with no scheduled replacements.

The primary endpoints were:

- **Safety:** Statistical equivalence in the proportion of total grade 2 or greater positive slit lamp findings, between the Test and Control lenses, was considered clinically acceptable.
- **Efficacy:** Statistical equivalence in the proportion of lens visual acuities at the level of 20/40 or better, between Test and Control lenses, was considered clinically acceptable.

There were no significant differences in the proportion of total grade 2 or greater slit lamp findings, for the category of Any Finding, between the Test and Control lenses (all p-values > 0.05). Therefore, the safety end-point defined in the protocol was achieved.

There were no significant differences in the proportion of lens visual acuities at the level of 20/40 or better between the Test and Control lenses (all p-values > 0.05). Therefore, the efficacy end-point defined in the protocol was achieved.

The Sponsor concludes, based on the data presented, that the protocol-specified endpoints were achieved, and that the Bausch & Lomb 2-Week Contact Lens is equivalent in safety and efficacy to the SofLens one day™ Contact Lens, when worn on a daily wear basis. The Bausch & Lomb 2-Week Contact Lens is a safe and effective means of daily wear vision correction.

Substantial Equivalence

The BAUSCH & LOMB® 2-Week (hilafilcon B) Visibility Tinted Contact Lens is similar to the BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon 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® 2-Week (hilafilcon B) Visibility Tinted Contact Lens is different from the BAUSCH & LOMB® SofLens™ one day disposable (hilafilcon A) Visibility Tinted Contact Lens in that it has a different USAN name suffix (hilafilcon B vs. hilafilcon A). The differences between these two lenses will not have any negative effect on the safety and effectiveness of the device.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bausch & Lomb Incorporated
Glenn A. Davies, O.D.
Director, Regulatory Affairs
1400 N. Goodman Street
Rochester, NY 14603-0450

Re: K994125
Trade Name: Bausch & Lomb 2-Week (hilafilcon B) Visibility Tinted
Contact Lens
Regulatory Class: II
Product Code: 86 LPL
Dated: December 6, 1999
Received: December 7, 1999

Dear Dr. Davies:

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): K994125

Device Name: BAUSCH & LOMB® 2-Week (hilafilcon B) Visibility Tinted Contact Lens

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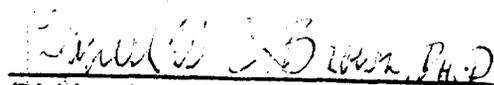
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

OR

Over-The-Counter-Use _____



(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K994125