

NOV 18 1998

K 983 894

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

FOR

BAUSCH & LOMB Phoenix (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 Phoenix (hilafilcon A) Visibility Tinted
Contact Lens

3. Predicate Device:

The BAUSCH & LOMB[®] SofLens[™] one day disposable (hilafilcon A) Visibility Tinted
Contact Lens has been selected as the predicate device.

4. Description of Device

The BAUSCH & LOMB Phoenix (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 Phoenix (hilafilcon) 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 Phoenix (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 Phoenix (hilafilcon A) 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.

The BAUSCH & LOMB Phoenix (hilafilcon A) Visibility Tinted Contact Lens may be prescribed for Frequent/Planned Replacement Wear. 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

The BAUSCH & LOMB Phoenix (hilafilcon A) Visibility Tinted Contact Lens has the same technological characteristics as the predicate device, the BAUSCH & LOMB[®] SofLens[™] one day disposable (hilafilcon A) Visibility Tinted Contact Lens. The established safety profile (toxicology, physicochemical properties, manufacturing / chemistry) of the BAUSCH & LOMB Phoenix (hilafilcon A) Visibility Tinted Contact Lens is equivalent to the predicate device.

The SofLens[™] one day disposable (hilafilcon A) Visibility Tinted Contact Lens was cleared on March 11, 1998, File Number K974780. File K974780 included test data from studies in which hilafilcon A visibility tinted contact lenses were subjected to care system testing, specifically 1) Compatibility testing of the lens care regimens recommended for use in the proposed labeling, and 2) Clinical performance testing.

The BAUSCH & LOMB Phoenix (hilafilcon A) Visibility Tinted Contact Lens is therefore substantially equivalent to the predicate device, the BAUSCH & LOMB[®] SofLens[™] one day disposable (hilafilcon A) Visibility Tinted Contact Lens, and does not raise new questions of safety or effectiveness.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BAUSCH & LOMB
Dennis Hahn
Manager, Regulatory Affairs
1400 North Goodman St.
Rochester, NY 14692

Re: K983894
Trade Name: Bausch & Lomb Phoenix (hilafilcon A) Visibility Tinted Contact Lens for
Daily Wear
Regulatory Class: II
Product Code: 86 LPL
Dated: October 30, 1998
Received: November 3, 1998

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 (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

