MAR 1 2 2004

510(k) Summary: K033919

1. Submitter Information:

Company: CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia USA 30097

Contact Person: Alicia M. Plesnarski, RAC
Director, Global Regulatory Affairs

Telephone: 678-415-3924
FAX: 678-415-3454

Date Prepared: 4 March 2004

2. Device Name:

- Common Name: Soft Contact Lens
- Trade/Proprietary Name: CIBA Vision® (lotrafilcon B)
- Classification Name: Daily Wear Soft Contact Lens
- Device Classification: Class II [21 CFR 886.5925 (b) (1)]

3. Predicate Device:

The CIBA Vision® (lotrafilcon B) lens is a modification in surface treatment of the predicate device, CIBA Vision's Excelens™ (lotrafilcon B) soft contact lens. Both are in FDA Group 1 (low water, nonionic polymer). CIBA Vision obtained FDA 510(k) clearance for Excelens™ (lotrafilcon B) lenses for daily wear on April 9, 2002 (K020139).

4. Description of Device:

The lens material is 33% water and 67% lotrafilcon B, a fluoro-silicone containing hydrogel which is surface treated.

Lotrafilcon B lens designs include spherical, toric, multifocal and toric multifocal lenses in the following parameter ranges:

- Diameter Range: 13.0 to 15.0 mm
- Base Curve Range: 8.0 to 9.2 mm
- Power Range: -20.00D to +20.00D
- Center Thickness: varies with power (0.080 mm for -3.00D spherical)

Lenses contain the color additive copper phthalocyanine, a light blue handling tint, which makes them easier to see when handling.

Lenses have the following properties:

- Refractive index: 1.42 (hydrated)
- Light transmittance: ≥ 96 %
- Water content : 33% by weight in normal saline
- Oxygen permeability 110×10^{-11} $[(cm^2/sec)(ml\ O_2/ml \bullet mmHg)]$ measured at 35°C (intrinsic Dk-Coulometric method)

Lenses are supplied sterile in sealed blister packs containing isotonic phosphate buffered saline solution. The compatibility and package integrity of the blister pack packaging system has been demonstrated and successfully used for other marketed lens products, and packaged lenses are effectively steam sterilized in a validated autoclave. Blister pack containers are labeled with the lens parameters, lot number and product expiration date. The expiration date has been established through stability studies that have assessed the chemical stability of the lens and package integrity (ability to maintain sterility). Shelf-life studies are ongoing to establish and extend the labeled expiration date.

5. Indications for Use:

The CIBA Vision® (lotrafilcon B) spherical soft contact lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and with up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

The CIBA Vision® Toric (lotrafilcon B) soft contact lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with 10.00 diopters (D) or less of astigmatism.

The CIBA Vision® Progressives (lotrafilcon B) soft contact lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 1.50 diopters of astigmatism.

The CIBA Vision® Progressive Toric (lotrafilcon B) soft contact lens is indicated for the optical correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in phakic or aphakic persons with non-diseased eyes. The lenses may be worn by persons who have 10.00 diopters (D) or less of refractive and/or corneal astigmatism.

The lenses may be prescribed for daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional.

6. Description of Safety and Substantial Equivalence:

A series of non-clinical tests and clinical studies were performed to demonstrate the substantial equivalence of the device modification and establish substantial equivalence to the predicate device. All testing was conducted in accordance with the May 1994 FDA guideline titled *Premarket Notification 510(k) Guidance Document for Class II Contact Lenses* and in conformance to applicable device regulations. Results verify that the modified lens remains non-toxic and biocompatible, and has material characteristics comparable to or better than other currently marketed soft contact lenses. Clinically, the lens has performed satisfactorily in a daily wear investigation. Results from all tests demonstrate the substantial equivalence to previously FDA approved predicate (control) lenses.

Nonclinical Testing:

A series of pre-clinical testing was performed to verify equivalence of the modified device of to the predicate device. Non-clinical biocompatibility testing was conducted in accordance with the GLP regulation (21 CFR Part 58).

The results of all non-clinical testing on the modified (lotrafilcon B) contact lens demonstrate:

- The lens material and extracts of the modified device are equivalent to the predicate and remain not toxic and non-irritating.
- Lens physical and material properties of the modified device are consistent with industry marketed lenses, and equivalent to the predicate lens.
- The lens material is compatible with commonly available lens care products.

Clinical Testing:

The (lotrafilcon B) contact lens was investigated in daily wear clinical study. The two-month clinical evaluation was conducted in accordance with current Good Clinical Practices and published regulations (21 CFR Parts 50, 56, 312, and 812). The study assessed the clinical performance of the modified lens as compared to an FDA approved and commercially available contact lens.

Clinical evaluation of the (lotrafilcon B) lens demonstrated similar overall performance in the clinically relevant areas of vision, health, comfort and fit as compared to the control lens when used under daily wear conditions.

Substantial Equivalence:

The modified (Iotrafilcon B) contact lens is equivalent to the predicate lens and similar to other daily wear soft contact lenses in terms of water content (33% water) and ionic characteristics (FDA Group I: low water, nonionic), clinical performance, and indications for use. In addition, the lenses may be disinfected using a chemical, not heat, disinfection regimen.

Any differences which may exist between the (Iotrafilcon B) soft contact lens and other Group I soft hydrophilic plastic contact lenses do not adversely affect the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2004

CIBA VISION
c/o Ms. Alicia M. Plesnarski, RAC
Director, Global Regulatory Affaire
11460 Johns Creek Parkway
Duluth, GA 30097-1556

Re: K033919
Trade/Device Name: CIBA Vision® (lotrafilcon B) Soft Contact Lenses for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: December 16, 2003
Received: December 18, 2003

Dear Ms. Plesnarski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K033919

Device Name: CIBA Vision® (lotrafilcon B) Soft Contact Lenses

Indications For Use:

The **CIBA Vision®** (lotrafilcon B) spherical soft contact lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and with up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

The **CIBA Vision®** Toric (lotrafilcon B) soft contact lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with 10.00 diopters (D) or less of astigmatism.

The **CIBA Vision®** Progressives (lotrafilcon B) soft contact lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 1.50 diopters of astigmatism.

The **CIBA Vision®** Progressive Toric (lotrafilcon B) soft contact lens is indicated for the optical correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in phakic or aphakic persons with non-diseased eyes. The lenses may be worn by persons who have 10.00 diopters (D) or less of refractive and/or corneal astigmatism.

The lenses may be prescribed for daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional.

Prescription Use: ☑ **AND/OR** **Over the Counter Use** ☐
(21 CFR Part 801 Subpart D) **(21 CFR Part 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K033919