APR 0 9 2002

K020139

| CIBA Vision. A Novartis Company | CIBA Vision® Corporation<br>11460 Johns Creek Parkway<br>Duluth, Georgia USA 30097 | 28-Mar-02, v02<br>Page 1 of 4 |
|---|---|---|
| **Lotrafilcon B Soft Contact Lenses**<br>510(k) – **K020139** Summary of Safety and Substantial Equivalence | | |

**510(k) Summary**

**1. Submitter Information:**

| | |
|---|---|
| Company: | CIBA Vision Corporation<br>11460 Johns Creek Parkway<br>Duluth, Georgia USA 30097 |
| Contact Person: | Alicia M. Plesnarski, RAC<br>Senior Specialist, Global Regulatory Affairs |
| Telephone: | 678-415-3924 |
| FAX: | 678-415-4333 |
| Date Prepared: | 28 March, 2002 |

**2. Device Name:**

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

**3. Predicate Device:**

The Focus® Excelens™ (lotrafilcon B) lens is a modification of the predicate device, (lotrafilcon A) soft contact lens. Both are in FDA Group 1 (low water, nonionic polymer). CIBA Vision obtained FDA 510(k) clearance for daily wear on May 9, 1997 (K970746) and FDA PMA marketing approval for extended wear on October 11, 2001 (P010019) for (lotrafilcon A) lenses.

**4. Description of Device:**

The material used for (lotrafilcon B) soft contact lenses is a modification to the lens material used for (lotrafilcon A) lenses. The lens material is 33% water and 67% lotrafilcon B, a silicone containing hydrogel which is surface treated.

Lotrafilcon B lens designs include spherical, toric and 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 $110 \times 10^{-11}$ $[(cm^2/sec)(ml\ O_2/ml \bullet mmHg)]$ measured at 35°C (intrinisic 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). Stability study data currently supports a twenty four (24) month shelf-life for (lotrafilcon B) soft contact lenses in sealed blister pack containers. Shelf-life studies are ongoing to determine extension of expiration dating.

## 5. Indications for Use:

Focus® Excelens™ (lotrafilcon B) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and with approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

Focus® Excelens™ Toric (lotrafilcon B) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with 6.00 diopters (D) or less of astigmatism.

Focus® Excelens™ Progressives (lotrafilcon B) soft contact lenses are 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 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 safety and effectiveness of the (lotrafilcon B) contact lens, and establish substantial equivalence to a currently marketed, predicate (lotrafilcon A) control lens. 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 demonstrate the lens is 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, and currently marketed predicate (control) lenses.

**Nonclinical Testing:**

A series of *in vitro* and *in vivo* pre-clinical toxicology and biocompatibility testing was performed to assess the safety and effectiveness of the contact lens. All non-clinical toxicology tests were conducted in accordance with the GLP regulation (21 CFR Part 58).

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

- The lens material and extracts are not toxic and non- irritating.
- Lens physical and material properties are consistent with industry marketed lenses, and similar to lotrafilcon A lenses.
- The lens material remains unaffected, with respect to lens properties, by exposure to chemical cleaning and disinfection systems, and is compatible with commonly available lens care products.

**Clinical Testing:**

The (lotrafilcon B) contact lens was investigated in daily wear clinical study. The one-month clinical evaluation was conducted in accordance with current Good Clinical Practices and published regulations (21 CFR Parts 50, 56, 312, 812). The study assessed the safety and effectiveness, and clinical performance as compared to the predicate control lens.

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

**Substantial Equivalence:**

The (lotrafilcon B) contact lens is 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 (lotrafilcon B) soft contact lens and other Group I soft hydrophilic plastic contact lenses does not adversely effect 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

APR - 9 2002

CIBA Vision Corporation
c/o Alicia M. Plesnarski, RAC
11460 Johns Creek Parkway
Duluth, GA 30097

Re: K020139
Trade/Device Name: Focus Excelens (lotrafilcon B) Soft Contact Lenses
Regulation Number: 21CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: January 15, 2002
Received: January 16, 2002

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

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

## INDICATIONS FOR USE STATEMENT

**510(k) Number:** K020139

**Device Name:** Focus® Excelens™ (Iotrafilcon B) Soft Contact Lenses

**Indications For Use:**

Focus® Excelens™ (Iotrafilcon B) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and with approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

Focus® Excelens™ Toric (Iotrafilcon B) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with 6.00 diopters (D) or less of astigmatism.

Focus® Excelens™ Progressives (Iotrafilcon B) soft contact lenses are 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 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.

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Daniel W. C. Brown, Ph.D.

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

**510(k) Number** K020139

**Prescription Use:** ☒ **or** **Over the Counter Use** ☐