 <small>Shared Passion for Healthy Vision and Better Life</small>	CIBA VISION Corporation 11460 Johns Creek Parkway Duluth, Georgia USA 30097	7-Dec-2007, v01 Page 1 of 3
Lotrafilcon B Soft Contact Lenses 510(k) Summary of Safety and Substantial Equivalence		

510(k) Summary

K073459

1. Submitter Information:

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

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

Telephone: 678-415-3924
Facsimile: 678-415-3454
Email: alicia.plesnarski@cibavision.com
Date Prepared: 7 December 2007

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 predicate device is the CIBA VISION® (lotrafilcon B) lens packaged in phosphate buffered saline. Lotrafilcon B lenses are in FDA Group 1 (low water, nonionic polymer). CIBA VISION obtained FDA Premarket Notification 510(k) Clearance for plasma treated (lotrafilcon B) lenses for daily wear on March 12, 2004 (K033919).

4. Description of Device:

The lens material is 33% water and 67% lotrafilcon B, a fluoro-silicone containing hydrogel which is surface treated. Lenses contain the color additive phthalocyanine blue, a light blue handling tint, which helps make them easier to see when handling.

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 design and power
(0.08 mm for -3.00D spherical)

Lotrafilcon B Soft Contact Lenses
510(k) Summary of Safety and Substantial Equivalence

Lenses have the following properties:

- Refractive index: 1.4217 (hydrated)
- Light transmittance: > 94 %
- Water content : 33% by weight in normal saline
- Oxygen permeability 110×10^{-11}
[(cm² /sec)(ml O₂ /ml•mmHg)]
measured at 35°C (intrinsic Dk-Coulometric method)

Lenses are supplied sterile in sealed blister packs containing isotonic phosphate buffered saline solution (PBS), or PBS with 1% Copolymer 845. 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:


CIBA VISION® (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.

CIBA VISION® 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.

CIBA VISION® Multifocal (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.

CIBA VISION® Multifocal Toric (lotrafilcon B) soft contact lenses are 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 6.00 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.

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6. Description of Safety and Substantial Equivalence:

A series of non-clinical tests were performed to demonstrate the substantial equivalence of the lenses packaged with the saline additive 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 lenses packaged with the saline additive remain non-toxic and biocompatible, and have material characteristics comparable to, or better than, other currently marketed soft contact lenses. Results from all tests demonstrate substantial equivalence to the previously FDA approved predicate (control) lenses.

Nonclinical Testing:


A series of nonclinical testing was performed to verify the equivalence of lenses packaged with saline additive 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 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 or better than the predicate lens.
- Finished lenses are compatible with commonly available lens care products.

Substantial Equivalence:

Lotrafilcon B soft contact lenses packaged in modified saline are 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) 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 contact lenses do not adversely affect the safety and effectiveness of the device.

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<p>Lotrafilcon A Soft Contact Lenses 510(k) Summary of Safety and Substantial Equivalence</p>		

510(k) Summary

K073459

1. Submitter Information:

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

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

Telephone: 678-415-3924
Facsimile: 678-415-3454
Email: alicia.plesnarski@cibavision.com
Date Prepared: 7 December 2007

2. Device Name:

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

3. Predicate Device:


The predicate device is the CIBA VISION® (lotrafilcon A) lens packaged in phosphate buffered saline. Lotrafilcon A lenses are in FDA Group 1 (low water, nonionic polymer). CIBA VISION obtained FDA Premarket Notification 510(k) Clearance for plasma treated (lotrafilcon A) lenses for daily wear on May 9, 1997 (K970746).

4. Description of Device:

The lens material is 24% water and 76% lotrafilcon A, a fluoro-silicone containing hydrogel which is surface treated. Lenses may be clear or contain the color additive copper phthalocyanine, a light blue handling tint, which makes them easier to see when handling.

Lotrafilcon A 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)

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<p>Lotrafilcon A Soft Contact Lenses 510(k) Summary of Safety and Substantial Equivalence</p>		

Lenses have the following properties:

- Refractive index: 1.4271 (hydrated)
- Light transmittance: > 94 %
- Water content : 24% by weight in normal saline
- Oxygen permeability 140 x 10⁻¹¹
[(cm² /sec)(ml O₂ /ml•mmHg)]
measured at 35°C (intrinsic Dk-Coulometric method)

Lenses are supplied sterile in sealed blister packs containing isotonic phosphate buffered saline solution (PBS), or PBS with 1% Copolymer 845. 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:


CIBA VISION® (lotrafilcon A) 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.

CIBA VISION® Toric (lotrafilcon A) 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 10.00 diopters (D) or less of astigmatism.

CIBA VISION® Multifocal (lotrafilcon A) 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.

CIBA VISION® Multifocal Toric (lotrafilcon A) soft contact lenses are 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.

In addition, CIBA VISION® (lotrafilcon A) lenses are also indicated for therapeutic use. Use as a bandage to protect the corneal and to relieve corneal pain in the treatment of acute or chronic ocular pathologies, such as bullous keratopathy, corneal erosions, entropion, corneal edema, and corneal dystrophies as well as post-surgical conditions

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Lotrafilcon A Soft Contact Lenses 510(k) Summary of Safety and Substantial Equivalence		

resulting from cataract extraction and corneal surgery. Lotrafilcon A soft contact lenses for therapeutic use can also provide optical correction during healing if required.

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 were performed to demonstrate the substantial equivalence of lenses packaged in phosphate buffered saline with additive to the predicate lens packaged in phosphate buffered saline only. 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 lenses remain non-toxic and biocompatible, and have material characteristics comparable to or better than other currently marketed soft contact lenses. Results from all testing demonstrates the substantial equivalence to previously FDA approved predicate (control) lenses.

Nonclinical Testing:

A series of nonclinical testing was performed to verify equivalence of lenses packaged in modified saline to the predicate device. Non-clinical biocompatibility testing was conducted in accordance with the GLP regulation (21 CFR Part 58). The results of all nonclinical testing 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.
- Finished lenses are compatible with commonly available lens care products.

Substantial Equivalence:

Lotrafilcon A soft contact lens packaged in modified saline are equivalent to the predicate lens and similar to other daily wear soft contact lenses in terms of water content (24% water) and ionic characteristics (FDA Group I: low water, nonionic) 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 A) soft contact lens and other Group I soft hydrophilic contact lenses do not adversely affect the safety and effectiveness of the device.



FEB 28 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K073459

Trade/Device Name: CIBA Vision® (lotrafilcon B) and (lotrafilcon A) Daily Wear Soft
Contact Lenses

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (hydrophilic) contact lens

Regulatory Class: II

Product Code: LPL

Dated: December 7, 2007

Received: December 10, 2007

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.

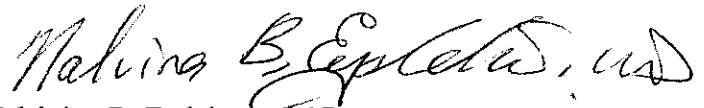
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, 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:

K073459

Device Name:

CIBA VISION® (Iotrafilcon B) Soft Contact Lenses

Indications For Use:

CIBA VISION® (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.

CIBA VISION® 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.

CIBA VISION® Multifocal (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.

CIBA VISION® Multifocal Toric (Iotrafilcon B) soft contact lenses are 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 6.00 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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chandramallika Ghosh

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

510(k) Number

K073459

Prescription Use:

or

Over the Counter Use

INDICATIONS FOR USE STATEMENT

510(k) Number: K073459
Device Name: CIBA VISION® (lotrafilcon A) Soft Contact Lenses

Indications For Use:

CIBA VISION® spherical (lotrafilcon A) 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.

CIBA VISION® toric (lotrafilcon A) 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 10.00 diopters (D) or less of astigmatism.

CIBA VISION® multifocal (lotrafilcon A) 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.

CIBA VISION® multifocal toric (lotrafilcon A) soft contact lenses are 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.

In addition, CIBA VISION® (lotrafilcon A) lenses are also indicated for therapeutic use. Use as a bandage to protect the corneal and to relieve corneal pain in the treatment of acute or chronic ocular pathologies, such as bullous keratopathy, corneal erosions, entropion, corneal edema, and corneal dystrophies as well as post-surgical conditions resulting from cataract extraction and corneal surgery. Lotrafilcon A soft contact lenses for therapeutic use can also provide optical correction during healing if required.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Chandramallika Bhash

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