# 510(K) SUMMARY
# AIR OPTIX® COLORS (lotrafilcon B)
# Contact Lenses
# 1/27/2013

## 1. *Submitter Information:*

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

Contact Person: Martina Heim, Ph.D., RAC
Senior Principal Regulatory Specialist

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Date Prepared: 20 December 2013

*With the merger between Alcon, Inc. and Novartis AG in April 2011, Ciba Vision Corporation and Alcon Laboratories, Inc. both became part of the newly formed Alcon eye care division within the Novartis group.

## 2. *Device Name:*

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

## 3. *Predicate Device:*

The predicate devices are Ciba Vision AIR OPTIX® AQUA (lotrafilcon B) soft contact lenses cleared under Premarket Notification 510(k) K073459 and Ciba Vision FreshLook ColorBlends® (phemfilcon A) soft contact lenses, approved for daily and extended wear under PMA P830037/S047.

## 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 is classified as a Group V (silicone hydrogel) hydrogel contact lens material according to ISO 18369-1:2006/Amd.1:2009. A cosmetic pattern is embedded into the back surface of the lens, containing a combination of the following color additives: iron oxides, titanium dioxide, [phthalocyaninato (2-)] copper, and phthalocyanine green.

Lens designs for AIR OPTIX® COLORS (lotrafilcon B) lenses include spherical, toric, and multifocal lenses in the following parameter range:

- Power Range: -20.00D to +20.00D
- Center Thickness: varies with design and power (0.08 mm for -3.00D spherical)
- Diameter Range: 13.0 to 15.0 mm
- Base Curve Range: 8.0 to 9.2 mm

Lenses have the following properties:

- Refractive index: 1.422 (hydrated)
- Light transmittance: > 95% (380 – 780 nm)
- Water content: 33% by weight in normal saline
- Oxygen permeability $110 \times 10^{-11}$ $(cm^2/sec)(ml\ O_2/ml \times mm\ Hg)$, 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 (labeled as buffered saline containing 0.2 % VP/DMAEMA Copolymer). 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 color and 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 further extend the labeled expiration date.

## 5. *Indications for Use:*

AIR OPTIX® COLORS (lotrafilcon B) spherical soft contact lenses are indicated for daily wear 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.

AIR OPTIX® COLORS Toric (lotrafilcon B) soft contact lenses are indicated for daily wear 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.

AIR OPTIX® COLORS Multifocal (lotrafilcon B) soft contact lenses are indicated for daily wear 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.

AIR OPTIX® COLORS (lotrafilcon B) lenses with or without refractive power act to enhance or alter the apparent color of the eye.

The lenses may be prescribed for frequent/planned replacement wear with daily 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:*

AIR OPTIX® COLORS differ from AIR OPTIX® AQUA by featuring a cosmetic pattern which is embedded into the lens surface and partially masks the natural eye color to provide an enhanced appearance. The cosmetic pattern is applied through an in-mold pad printing process. The following tables summarize the characteristics of the modified device as compared to the predicate devices:

**Product comparison:**

| | **Modified Device** | **Predicate Device** | **Predicate Device** |
|---|---|---|---|
| | **AIR OPTIX® COLORS** | **AIR OPTIX® AQUA** | **FreshLook ColorBlends** |
| **Submission #** | **To be assigned** | **K073459 / P010019** | **P830037/S047** |
| **Intended Use** | Vision Correction<br>With or without refractive power: Enhance or alter the apparent color of the eye | Vision Correction<br>N/A | Vision Correction<br>With or without refractive power: Enhance or alter the apparent color of the eye |
| **Wearing Schedule** | Daily Wear | Daily and Extended Wear | Daily Wear recommended |
| **Material Classification:** | Group V (silicone hydrogel) hydrogel contact lens material according to ISO 18369-1:2006/.1:2009 | Group V (silicone hydrogel) hydrogel contact lens material according to ISO 18369-1:2006/.1:2009 | FDA Group 4 (> 50% $H_2O$, ionic polymer) |
| **Lens Material:** | lotrafilcon B | lotrafilcon B | phemfilcon A |
| **Surface treatment** | plasma treated | plasma treated | N/A |

**Technological characteristics:**

| | Modified Device | Predicate Device | Predicate Device |
|---|---|---|---|
| | **AIR OPTIX® COLORS** | **AIR OPTIX® AQUA** | **FreshLook ColorBlends** |
| **Submission #** | **To be assigned** | **K073459 / P010019** | **P830037/S047** |
| **Manufacturing Method:** | Double-side molding integrated print step | Double-side molding | Double-side molding integrated print step |
| **Print technology** | In-mold pad print technology | N/A | Pad print technology on lens surface |
| **Color additives for print:** | PCN Green<br>PCN Blue<br>Titanium dioxide<br>Yellow iron oxide<br>Red iron oxide<br>Black iron oxide | N/A | PCN Green<br>PCN Blue<br>Titanium dioxide<br>Yellow iron oxide<br>Red iron oxide<br>Black iron oxide<br>Brown iron oxide<br>Chromium oxide<br>Carbazole violet<br>Mica coated with IO<br>Mica coated with $TiO_2$ |
| **Visibility Tint:** | N/A | PCN Blue | PCN Green (optional) |
| **Lens Designs:** | Spherical, toric, multifocal | Spherical, toric, multifocal | Spherical, toric |
| **Sterilization:** | Steam sterilization, validated autoclave | Steam sterilization, validated autoclave | Steam sterilization, validated autoclave |
| **Packaging:** | Blister pack | Blister pack | Blister pack |
| **Package Storage saline solution** | Phosphate buffered saline with (or without) 1% Copolymer 845 | Phosphate buffered saline with (or without) 1% Copolymer 845 | Borate buffered saline with 0.005% poloxamer |

**Parameter comparison:**

| | Modified Device | Predicate Device | Predicate Device |
|---|---|---|---|
| | **AIR OPTIX® COLORS** | **AIR OPTIX® AQUA** | **FreshLook ColorBlends** |
| **Submission #** | **To be assigned** | **K073459 / P010019** | **P830037/S047** |
| **Water Content:** | 33% | 33% | 55% |
| **Power Range:** | +20.00 to -20.00D | +20.00 to -20.00D | +20.00 to -20.00D for daily wear |
| **Base Curve Range** | 8.0 to 9.2 mm | 8.0 to 9.2 mm | 7.80 to 9.00 mm |
| **Diameter Range** | 13.0 to 15.0 mm | 13.0 to 15.0 mm | 12.0 to 15.0 mm |
| **Refractive Index** | 1.422 | 1.422 | 1.409 |
| **Oxygen Permeability*** | 110* | 110* | 16.1** |

* x $10^{-11}$ ($cm^2$/sec)(ml $O_2$ /ml x mm Hg); measured at 35°C (intrinsic Dk-Coulometric method)

** x $10^{-11}$ (cm/s)[ml O2/(ml · mmHg] at 35 °C (Dr. Irving Fatt Method)

Non-clinical Testing:

A series of non-clinical testing was performed to characterize the lens material properties of AIR OPTIX® COLORS and demonstrate the substantial equivalence of the new device 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:

- Physicochemical characteristics of the modified device are substantially equivalent to the predicate lens, AIR OPTIX® AQUA.
- The lens material and extracts of the modified device are substantially equivalent to the predicate device and are non-toxic and non-irritating.

Successful stability testing supports the labeled expiration date.

Clinical Testing:

The subjective and objective performance and the physiological response of AIR OPTIX® COLORS soft contact lenses was evaluated in a 3-month prospective, randomized, controlled, open-label, parallel-group, multi-center study. A total of one hundred forty seven (147) subjects were enrolled and randomized to wear either test AIR OPTIX® COLORS (lotrafilcon B) or control AIR OPTIX® AQUA (lotrafilcon B) soft contact lenses, following a 2:1 subject allocation ratio as recommended by EN ISO 11980:2009 and the US FDA *Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses*, May 1994. This study consisted of 7 scheduled visits conducted over a 3 month period.

The primary efficacy variable of this trial was visual acuity. The secondary efficacy variables were subjective ratings of vision, comfort, and handling, lens fit, and lens surface characteristics. The safety variables of this trial were biomicroscopy findings, discontinuations (excluding cosmetic reasons), and all ocular adverse events.

Summary

The AIR OPTIX® COLORS and AIR OPTIX® AQUA lenses performed comparably during this study. In general, biomicroscopic findings, visual acuity, fit characteristics, lens surface

performance, and subjective assessments were similar in the AIR OPTIX® COLORS and AIR OPTIX® AQUA groups. The study demonstrated substantial equivalence of AIR OPTIX® COLORS lenses to AIR OPTIX® AQUA lenses, the predicate device.

**Substantial Equivalence:**

AIR OPTIX® COLORS (lotrafilcon B) soft contact lenses packaged are equivalent to the predicate device lenses and similar to other daily wear soft contact lenses in terms of material properties, biocompatibility, clinical performance, and indications for use.

Any differences which may exist between AIR OPTIX® COLORS lenses and the predicate devices do not adversely affect the established performance characteristics and safety and effectiveness profile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 12, 2014

CIBA Vision Corporation
% Martina Heim, Ph.D., RAC
Senior Principal Regulatory Specialist
11460 Johns Creek Parkway
Duluth, GA 30097

Re: K133176
Trade/Device Name: AIR OPTIX® COLORS (lotrafilcon B)
Regulation Number: 21 CFR 886.5925
Regulation Name: Daily Wear Soft (Hydrophilic) Contact Lenses
Regulatory Class: Class II
Product Code: LPL
Dated: December 20, 2013
Received: December 23, 2013

Dear Dr. Heim:

This letter corrects our substantially equivalent letter of January 29, 2014.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement on last page.*

510(k) Number *(if known)*
K133176

Device Name
AIR OPTIX® COLORS (lotrafilcon B) Soft Contact Lens

Indications for Use *(Describe)*
AIR OPTIX® COLORS (lotrafilcon B) spherical soft contact lenses are indicated for daily wear 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.

AIR OPTIX® COLORS Toric (lotrafilcon B) soft contact lenses are indicated for daily wear 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.

AIR OPTIX® COLORS Multifocal (lotrafilcon B) soft contact lenses are indicated for daily wear 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.

AIR OPTIX® COLORS (lotrafilcon B) lenses with or without refractive power act to enhance or alter the apparent color of the eye.

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jeffrey M. Brocious -S
2014.02.05 13:09:13 -05'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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