October 25, 2017

Alcon Laboratories, Inc.
Martina Heim, Ph.D., RAC
Director, Global Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K172600
Trade/Device Name: AIR OPTIX COLORS®
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: August 25, 2017
Received: August 30, 2017

Dear Martina Heim, Ph.D., RAC:

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 Industry and Consumer Education (DICE) 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" (21 CFR 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 Industry and Consumer Education (DICE) 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,

Denise L. Hampton -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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172600

Device Name

AIR OPTIX® COLORS soft contact lenses

Indications for Use *(Describe)*

AIR OPTIX® COLORS (lotrafilcon B) spherical soft contact lenses with refractive power 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 up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

AIR OPTIX® COLORS (lotrafilcon B) toric 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 (lotrafilcon B) multifocal 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary

This 510(k) summary document has been prepared in accordance with section 21 CFR 807.92.

I. Submitter of the 510(k)

Company:	Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX 76134-2099, USA
Primary Contact Person:	Martina Heim, Ph.D., RAC Director, Global Regulatory Affairs
Phone:	678-415-3565
Fax:	678-415-3454
Email:	martina.heim@alcon.com
Date Prepared:	21 August 2017

II. Devices Subject to this 510(k)

Trade Names:	AIR OPTIX® COLORS
Common Name:	Soft Contact Lens
Classification Name:	Soft (Hydrophilic) Contact Lenses
Device Classification:	Class II [21 CFR 886.5925 (b) (1)]
Product Code:	LPL

III. Predicate Device

The subject device, AIR OPTIX® COLORS (lotrafilcon B) soft contact lenses, is a modification of the currently commercialized AIR OPTIX® COLORS contact lens. The predicate AIR OPTIX® COLORS soft contact lenses have received FDA clearance per Premarket Notification 510(k) K133176.

IV. Device Description

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: carbazole violet, iron oxides, [phthalocyaninato (2-)] copper, phthalocyanine green and titanium dioxide.

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

- 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)

Lenses have the following properties:

- Refractive index: 1.42 (hydrated)
- Luminous transmittance: 95 ± 5%
- Water content: 33% by weight in normal saline
- Oxygen permeability 110×10^{-11} (cm^2/sec)(ml O_2 /ml x 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 parameters, lens color, 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.

V. Indications for Use

AIR OPTIX® COLORS (lotrafilcon B) spherical soft contact lenses with refractive power 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 up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

AIR OPTIX® COLORS (lotrafilcon B) toric 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 (lotrafilcon B) multifocal soft contact lenses are indicated for daily wear for the optical correction of presbyopia with or without refractive ametropia (myopia and hyperopia) 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.

VI. Comparison to Technological Characteristics with the Predicate Device

New color options are being added to the line of AIR OPTIX® COLORS (lotrafilcon B) soft contact lenses. Key product characteristics remain unchanged, as listed in **Table 1**. Carbazole violet is added to the list of color additives that are used to achieve the desired shade variations in the cosmetic print pattern.

Table 1. Substantial Equivalence Comparison

	Predicate Device	Modified Device
Administrative / Regulatory Information		
Trade Name	**AIR OPTIX® COLORS**	Same
Submission number	K133176	*510(k) # to be assigned*
Device Classification Name	Daily Wear Soft Contact Lens 21 CFR 886.5925 (b) (1)	Same
Indications For Use Information		
Intended Use	*With refractive power:* Vision Correction	Same
	With or without refractive power: Enhance or alter the apparent color of the eye	Same
Wearing Schedule	Daily Wear	Same
Replacement Schedule	Up to Monthly Replacement	Same
Material and Technology Information		
Lens Material	lotrafilcon B	Same
Surface Treatment	Plasma treated	Same
Manufacturing Method	Double-side molding; integrated print step	Same
Print Technology	In-mold pad print technology	Same
Color Additives for Print:	PCN green PCN blue Titanium dioxide Yellow iron oxide Red iron oxide Black iron oxide	PCN green PCN blue Titanium dioxide Yellow iron oxide Red iron oxide Black iron oxide Carbazole violet
Water Content	33%	Same
Refractive Index	1.42	Same
Oxygen Permeability	~110*	Same
Sterilization	Steam sterilization, validated autoclave	Same

Table 1. Substantial Equivalence Comparison

	Predicate Device	Modified Device
Packaging	Blister pack	Same
Package Storage Saline Solution	Phosphate buffered saline with (or without) 1% Copolymer 845	Same
Lens Design and Parameters		
Lens Designs	Spherical, toric, multifocal	Same
Power Range	+20.00 to -20.00D	Same
Base Curve Range	8.0 to 9.2 mm	Same
Diameter Range	13.0 to 15.0 mm	Same

* intrinsic Dk - Coulometric method; barrer units

VII. Performance Data

Performance testing was conducted in consideration of the May 1994 FDA guideline titled Premarket Notification 510(k) Guidance Document for Class II Contact Lenses. The following performance data are provided in support of the substantial equivalence determination:

Non-clinical Testing

A series of non-clinical testing was performed to characterize the lens material properties of AIR OPTIX® COLORS lenses and demonstrate the substantial equivalence of the modified 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® COLORS.
- The modification does not impact the established safety profile for AIR OPTIX® COLORS soft contact lenses.

Successful stability testing supports the labeled expiration date.

Clinical Testing

The scope of the device modification did not require clinical testing to establish safety and effectiveness of the modified device.

VIII. Conclusions

AIR OPTIX® COLORS (lotrafilcon B) soft contact lenses as modified are equivalent to the predicate device lenses and similar to other daily wear soft contact lenses in terms of technological characteristics and intended use.

Non-clinical data demonstrates that the modified device is as safe, as effective, and performs as well as or better than the legally marketed, predicate device, AIR OPTIX® COLORS soft contact lenses.