September 15, 2022

Alcon Laboratories, Inc.
Dr. Andreas Friese
Regulatory Project Director
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K222500
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 17, 2022
Received: August 18, 2022

Dear Dr. Andreas Friese:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

J. Angelo Green, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222500

Device Name
AIR OPTIX COLORS

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 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.

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.

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510(k) Summary

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

510(k) number: K222500

I. Submitter Information

Company:	Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX 76134-2099, USA
Contact Person:	Dr. Andreas Friese Regulatory Project Director
Phone:	+49 6022-240-514
Fax:	+49 6022-240-512
Email:	andreas.friese@alcon.com
Date Prepared:	August 16, 2022

II. Devices Subject to this 510(k)

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

III. Predicate Device

The 510(k) devices are a modification of the same predicate devices, i.e., AIR OPTIX® COLORS (lotrafilcon B) soft contact lenses, which are legally commercialized devices in the US per the following most recent US FDA 510(k) clearance: K172600.

IV. Device Description

The lens material of AIR OPTIX® COLORS is 33% water and 67% lotrafilcon B, a fluoro-silicone containing hydrogel which is surface treated. Lotrafilcon B is classified as a Group 5 (silicone hydrogel) hydrogel contact lens material according to ISO 18369-1:2017. 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.

Cleared lens designs for AIR OPTIX® COLORS (lotrafilcon B) 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: -20.00 D to +20.00 D
- Center Thickness: varies with design and power (0.08 mm for -3.00 D 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 phosphate buffered saline solution (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 of Technological Characteristics with the Predicate Device

The proposed device modification involves adding an alternate foil lidding material for use in the primary packaging of AIR OPTIX® COLORS (lotrafilcon B) soft contact lenses. The following matrix (**Table 1**) summarizes the characteristics of the modified devices as compared to the predicate devices.

Table 1: Substantial Equivalence Comparison

Element of Comparison	Predicate Device(s)	Modified Device(s)
Administrative / Regulatory Information		
Trade Name(s)	AIR OPTIX® COLORS	Same
510(k) Number	K172600	*To be assigned*
Device Classification Name	Daily Wear Soft Contact Lens 21 CFR 886.5925 (b) (1)	Same

Table 1: Substantial Equivalence Comparison

Element of Comparison	Predicate Device(s)	Modified Device(s)
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	
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 Carbazole violet	Same
Water Content	33%	Same
Refractive Index	1.42	Same
Oxygen Permeability	~110*	Same
Sterilization	Steam sterilization, validated autoclave	Same
Primary Packaging System	Foil blister pack: polypropylene blister shell sealed with a polyester coated aluminum foil lidding	Same

Table 1: Substantial Equivalence Comparison

Element of Comparison	Predicate Device(s)	Modified Device(s)
Primary Packaging Blister Shell	Injection-molded poly-propylene (PP) blister shell	Same
Primary Packaging Foil Lidding	Multi-layer laminate structure polyester-coated aluminum foil lidding supplied by: • Amcor	Multi-layer laminate structure polyester-coated aluminum foil lidding supplied by: • Amcor • Constantia-Pirk
Package Storage Saline Solution	Phosphate buffered saline (with or without) 1% Copolymer 845	Same
Lens Design and Parameter		
Lens Designs	Spherical, toric, multifocal	Same
Power Range	+20.00 to -20.00 D	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

In accordance with the criteria for claims of substantial equivalence in the FDA guidance *Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses*, May 1994, the information provided supports the claim of substantial equivalence to a lens with an existing USAN and the same manufacturing process.

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

To verify equivalence of the modified device to the predicate device (AIR OPTIX® COLORS lotrafilcon B soft contact lenses), successful stability and biocompatibility testing as well as process validation were completed for representative lotrafilcon B soft contact lenses produced/packaged with the Constantia lidding foil. Testing resulted in all acceptance criteria being met.

Clinical Testing

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

VIII. Conclusions

The cumulative results of all performance testing demonstrate the safety, efficacy and performance of the modified device(s) and, thus, substantial equivalence to the predicate device(s).

AIR OPTIX® COLORS (lotrafilcon B) spherical soft contact lenses in modified primary packaging including the proposed alternate 'Constantia Pirk' foil lidding material are substantially equivalent to the predicate lenses in terms of material properties, biocompatibility, shelf-life/expiration dating, clinical performance, and indications for use.

Any differences which may exist between the modified and the predicate device do not adversely affect the established performance characteristics and safety and effectiveness profile.