August 03, 2018

Alcon Laboratories, Inc.
Andreas Friese
Regulatory Project Director, GRA Alcon Vision Care
Alcon/CIBA Vision GmbH
Industriering 1
Grosswallstadt, Bavaria 63868
Germany

Re: K181796
Trade/Device Name: FreshLook Handling Tint, FreshLook Colors, FreshLook ColorBlends, FreshLook Dimensions
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: June 28, 2018
Received: July 5, 2018

Dear 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Scott E. Steffen -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)*
K181796

Device Name
FreshLook Handling Tint, FreshLook Colors, FreshLook ColorBlends, FreshLook Dimensions

Indications for Use *(Describe)*
FreshLook Spherical (phemfilcon A) soft (hydrophilic) contact lenses are indicated for the correction of visual acuity in persons with nondiseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 2.0 diopters that does not interfere with visual acuity.

The FreshLook Spherical Colors, ColorBlends, and Dimensions lenses act to enhance or alter the apparent color of the eye.

The eye care professional may prescribe the lens for frequent replacement with daily removal for cleaning and disinfection. The lens may be disinfected using a chemical disinfection system.

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.

I. Submitter Information

Company:	Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX 76134-2099, USA
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Date Prepared:	August 03, 2018

II. Devices Subject to this 510(k)

Trade Names:	*Soft Contact Lenses for Daily Wear (phemfilcon A material):* FreshLook Handling Tint, FreshLook Colors, FreshLook ColorBlends, FreshLook Dimensions
Common Name:	Soft Contact Lenses
Classification Name:	Soft (Hydrophilic) Contact Lenses
Device Classification:	Class II [21 CFR 886.5925]
Product Code:	LPL

III. Predicate Device

The 510(k) devices are a modification of the same predicate devices, i.e. FreshLook Handling Tint, FreshLook Colors, FreshLook ColorBlends and FreshLook Dimensions (phemfilcon A) soft contact lenses, which are legally commercialized devices in the US under 510(k) P830037.

IV. Device Description

FreshLook (phemfilcon A) are a family of soft contact lenses, intended for the optical correction of refractive error. The lenses are available in spherical designs and in the

following lens models: FreshLook Handling Tint, FreshLook Colors, FreshLook ColorBlends and FreshLook Dimensions.

FreshLook contact lenses are made of phemfilcon A lens material, a hydrophilic copolymer of 2-hydroxyethyl methacrylate (HEMA) and 2-ethoxyethyl methacrylate (EOEMA). The lenses have a water content of 55% by weight.

FreshLook Colors and FreshLook ColorBlends lenses are made of clear lens material, FreshLook Handling Tint and FreshLook Dimensions are made of tinted (green handling tint) lens material polymer to facilitate lens visibility for handling.

FreshLook Colors, FreshLook ColorBlends and FreshLook Dimensions lenses are printed with an intermittent coating containing color additives listed in the color additive provisions of 21 CFR. FreshLook Colors are available in the colors Blue, Green, Hazel, Misty Gray, Sapphire Blue and Violet. FreshLook ColorBlends are available in the colors Amethyst, Blue, Brown, Gray, Green, Honey, Pure Hazel, True Sapphire, Turquoise, Gemstone Green, Brilliant Blue and Sterling Gray. FreshLook Dimensions are available in the colors Caribbean Aqua, Pacific Blue and Sea Green.

FreshLook soft contact lenses are supplied sterile. The lenses immersed in 2.5 ml isotonic borate buffered saline solution are packaged in individual foil-blister packs and are terminally sterilized in a validated autoclave (moist heat, steam under pressure). The packaging saline contains 0.005% Poloxamer.

The foil-blister pack system consists of a thermo-formed array bottom made from polypropylene resin, sealed with an aluminum-based foil lidding. The blister packs are packaged into carton boxes available in different pack sizes.

V. Indications for Use

The 510(k) devices are a modification of the same predicate devices. The Indications for Use remain the same, as follows:

FreshLook Spherical (phemfilcon A) soft (hydrophilic) contact lenses are indicated for the correction of visual acuity in persons with nondiseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 2.0 diopters that does not interfere with visual acuity.

The FreshLook Spherical Colors, ColorBlends, and Dimensions lenses act to enhance or alter the apparent color of the eye.

The eye care professional may prescribe the lens for frequent replacement with daily removal for cleaning and disinfection. The lens may be disinfected using a chemical disinfection system.

VI. Comparison of Technological Characteristics with the Predicate Device

The proposed device modification involves adding an alternate foil lidding material grade from an existing approved supplier for use in the primary packaging (i.e. foil-blister pack container system) of FreshLook family soft contact lenses.

The following matrix (Table 1) summarizes the characteristics of the modified device as compared to the predicate device.

Table 1: Substantial Equivalence Comparison

Element of Comparison	Predicate Device	Modified Device
Administrative / Regulatory Information		
510(k) Number	510(k) (P830037)	K181796
Product Name(s)	FreshLook Handling Tint, FreshLook Colors, FreshLook ColorBlends, FreshLook Dimensions	Same
Device Classification Information	Class II, Soft (Hydrophilic) Contact Lenses, 21 CFR 886.5925	Same
Indications For Use Information		
Intended Use	Daily wear frequent replacement soft contact lenses for the optical correction of refractive error	Same
Technology Information		
Lens Material	phemfilcon A	Same
Material Classification	FDA Group 4 (≥ 50% H_2O, ionic polymer)	Same
Water Content	55%	Same
Visibility Tint	FreshLook Handling Tint and FreshLook Dimensions: Light green tint; FreshLook Colors and FreshLook ColorBlends: No tint	Same
Manufacturing Method	Double Sided Molding	Same
Lens Designs	Spherical	Same
Sterilization	Steam sterilization, validated autoclave	Same

Table 1: Substantial Equivalence Comparison

Element of Comparison	Predicate Device	Modified Device
Primary Packaging System	Foil blister pack container system: Polypropylene blister shell sealed with an aluminum-based foil lidding	Same
Primary Packaging: Blister Shell	Injection-molded polypropylene blister shell	Same
Primary Packaging: Foil Lidding	Constantia-Hueck foil lidding - Current grade	Constantia-Hueck foil lidding – Modified grade
Package Storage / Saline Solution	Isotonic, borate buffered saline containing 0.005% Poloxamer	Same
Performance Specifications including any Testing		
Refractive Index	1.412	Same
Light Transmittance	95% minimum at 600 nm	Same
Oxygen Transmissibility	Dk/L = 20 x 10-9 (cm/s)[ml O2/(ml • mmHg] at 35 °C	Same
Biocompatibility	Biocompatible as confirmed by biocompatibility testing	Same
Shelf-life	60 months as confirmed by shelf-life stability testing	Same

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

Successful stability and biocompatibility testing as well as process validation were completed for the modified device to verify equivalence to the predicate device. This 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 and, thus, substantial equivalence to the predicate device.

Freshlook brand (phemfilcon A) soft contact lenses in modified primary packaging are substantially equivalent to the predicate lenses in terms of material properties, biocompatibility, 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.