February 6, 2019

Alcon Laboratories, Inc.
Heather Smith
Regulatory Affairs Specialist
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K190045
Trade/Device Name: DAILIES® Colors, DAILIES® Colors Toric, DAILIES® Colors Progressives
Alternate family trade name: FreshLook® One-Day color contact lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: January 3, 2019
Received: January 9, 2019

Dear Heather Smith:

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,

J Angelo Green -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)*
K190045

Device Name
DAILIES® Colors; DAILIES® Colors Toric; DAILIES® Colors Progressives
Alternate family trade name: FreshLook® One-Day color contact lenses

Indications for Use *(Describe)*
DAILIES® Colors (nelfilcon A) One-Day Contact Lenses with refractive power, are indicated for the optical correction of refractive ametropia (myopia, hyperopia) in not-aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

DAILIES® Colors Toric (nelfilcon A) One-Day Contact Lenses are indicated for daily disposable wear for the optical correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes with 6.00 diopters (D) or less of astigmatism.

DAILIES® Colors Progressives (nelfilcon A) One-Day Contact Lenses are indicated for the optical correction of presbyopia, with or without refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity.

DAILIES® Colors (nelfilcon A) One-Day Contact Lenses (with or without corrective power) also act to enhance or alter the apparent color of the eye.

DAILIES® Colors (nelfilcon A) One-Day Contact Lenses are to be prescribed for single-use daily disposable wear (less than 24 hours while awake) only. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

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 of the 510(k)

Company:	Alcon Laboratories, Inc.
	6201 South Freeway
	Fort Worth, TX 76134-2099, USA
Primary Contact Person:	Heather Smith
Phone:	(678) 415-6884
Fax:	n/a
Email:	Heather.Smith@alcon.com
Back up Contact Person:	Martina Heim
Phone:	(678) 415 3565
Fax:	n/a
Email:	Martina.Heim@alcon.com
Date Prepared:	03 January 2019

II. Devices Subject to this 510(k)

Trade Names:	DAILIES® Colors
	DAILIES® Colors Progressives
	DAILIES® Colors Toric
	Alternate family trade name: FreshLook® One-Day color contact lenses
Common Name:	Soft Contact Lens
Classification Name:	Soft (Hydrophilic) Contact Lens [for daily wear]
Device Classification:	Class II [21 CFR 886.5925 (b)(1)]
Product Code:	LPL, MVN

III. Predicate Device

The predicate lens FreshLook® One-Day (nelfilcon A) colors contact lenses received FDA clearance under Premarket Notification 510(k) K050213, with recent updates cleared under K180398 and K180669.

IV. Device Description

The subject device, DAILIES Colors contact lenses, are a modification of the currently commercialized FreshLook® One-Day (nelfilcon A) color contact lenses. DAILIES Colors are soft contact lenses intended for the optical correction of refractive error, and the enhancement or alteration of the apparent color of the eye. Geometries include spherical, toric, and multifocal lens designs.

DAILIES Colors lenses are composed of nelfilcon A, which is a non-ionic, hydrophilic lens material, that consists of approximately 69% water and 31% PVA (polyvinyl alcohol partially acetalized with N-formylmethyl acrylamide). The lenses are pad printed with intermittent ink layers containing a combination of the following color additives, approved for use in color contact lenses: chromium oxide, iron oxides, [phthalocyaninato (2-)] copper, phthalocyanine green, and titanium dioxide.

Lens designs for DAILIES Colors (nelfilcon A) 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 (0.100 mm for -3.00D spherical)

Lenses have the following properties:

- Refractive index: 1.38 (hydrated)
- Water content: 69% by weight in normal saline
- Oxygen permeability 26 barrer units at 35 °C (Fatt corrected)
- % Light transmittance > 88% (average over 380-780 nm)

Lenses are provided in sterile packages of foil-sealed blister-packs containing buffered saline.

V. Indications for Use

DAILIES® Colors (nelfilcon A) One-Day Contact Lenses, with refractive power, are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.

DAILIES® Colors Toric (nelfilcon A) One-Day Contact Lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes with 6.00 diopters (D) or less of astigmatism.

DAILIES® Colors Progressives (nelfilcon A) One-Day Contact Lenses are indicated for the optical correction of presbyopia, with or without refractive ametropia (myopia and hyperopia), in not-aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity.

DAILIES® Colors (nelfilcon A) One-Day Contact Lenses (with or without corrective power) also act to enhance or alter the apparent color of the eye.

DAILIES® Colors (nelfilcon A) One-Day Contact Lenses are to be prescribed for single-use daily disposable wear (less than 24 hours while awake) only. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

VI. Comparison to Technological Characteristics with the Predicate Device

The design modification for DAILIES Colors involves addition of a modified print pattern, with a larger, more pronounced outer diameter and a less pronounced inner print pattern, utilizing the same, currently approved color additives as applied in FreshLook One-Day color contact lenses.

The following table summarizes the characteristics of the modified device as compared to the commercially available predicate device.

Table 1: Substantial Equivalence Comparison

	Predicate Device	Modified Device
Trade Name (brand)	FreshLook® One-Day	*Additional (alternate) trade name:* DAILIES® Colors
510(k)	K050213	K190045
Device Classification Information	Class II [21 CFR 886.5925 (b)(1)]	Same
Intended Use	With refractive power: Vision correction	Same
	With or without refractive power: Enhancement or alteration of the apparent color of the eye	Same
Wearing schedule	Daily wear	Same
Replacement schedule	Daily disposable	Same
Material Classification	Group 2 (>50% H_2O, nonionic polymer), according to ISO 18369-1: 2017	Same
Lens Material	Nelfilcon A	Same
Power Range	-20.00D to +20.00D	Same
Print technology	In-mold pad print technology	Same
Color Additives	Chromium Oxide, Iron oxides, [phthalocyaninato (2-)] copper, phthalocyanine green, Titanium Dioxide	Same
Water Content	69%, by weight	Same
Light Transmittance	> 88%T	Same
Refractive Index	1.38	Same
Oxygen Permeability	26 barrer units @ 35 °C	Same
Manufacturing Method	Lightstream Technology: Full mold cast, integrated print step	Same
Sterilization	Steam sterilization in validated autoclave	Same
Biocompatibility	Biocompatible as confirmed by appropriate biocompatibility testing	Same
Packaging	Blister pack	Same
Package Storage Saline Solution	Phosphate-acetate buffered saline solution with up to 0.05% Poloxamer 108	Same

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

VII. Performance Data

Performance testing was conducted in consideration of the May 1994 FDA Guidelines entitled *Premarket Notification 510(k) Guidance Document for Class II Contact Lenses.* The modified device underwent a successful process validation to verify equivalence to the predicate device. Results met the acceptance criteria accordingly.

Non-clinical testing

Successful 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.

Stability testing for the predicate device continues to support the labeled expiration date.

Clinical testing

The scope of the device modification did not necessitate clinical testing, in order to establish safety or efficacy.

Substantial Equivalence

DAILIES® Colors, DAILIES® Colors Toric, and DAILIES® Colors Progressives (nelfilcon A) one-day contact lenses are substantially equivalent to the predicate lenses and similar to other daily wear contact lenses, in terms of water content (69% water, by weight) and ionic characteristics (FDA Group II (>50% H_2O, non-ionic polymer)).

VIII. Conclusions

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

DAILIES Colors (nelfilcon A) one day contact lenses, with a modified print pattern, are substantially equivalent to the predicate lens in terms of material properties, biocompatibility, clinical performance, and indications for use.