August 21, 2020

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

Re: K202036
Trade/Device Name: Focus DAILIES / Focus DAILIES Toric / Focus DAILIES Progressives, DAILIES AquaComfort Plus (DACP) / DACP FreshTech / DACP Toric / DACP Multifocal
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: MVN, LPL
Dated: July 16, 2020
Received: July 23, 2020

Dear Mr. 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,

for Angelo Green, PhD
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)*

K202036

Device Name

Focus DAILIES, Focus DAILIES Toric, Focus DAILIES Progressives
DAILIES AquaComfort Plus, DAILIES AquaComfort Plus FreshTech, DAILIES AquaComfort Plus Toric, DAILIES AquaComfort Plus Multifocal

Indications for Use *(Describe)*

Focus DAILIES and Focus DAILIES Toric (nelfilcon A) One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with nondiseased eyes.

Focus DAILIES Progressives (nelfilcon A) One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or presbyopia in not-aphakic persons with non-diseased eyes who 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.

The lenses are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

DAILIES AquaComfort Plus and DAILIES AquaComfort Plus FreshTech (nelfilcon A) One-Day Contact Lenses are indicated for daily wear 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 AquaComfort Plus Toric (nelfilcon A) One-Day Contact Lenses are indicated for daily 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 AquaComfort Plus Multifocal (nelfilcon A) One-Day Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or presbyopia 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.

All DAILIES AquaComfort Plus (nelfilcon A) One-Day Contact Lenses are to be prescribed for single use, daily disposable wear. 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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8 510(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
Contact Person:	Dr. Andreas Friese, Regulatory Project Director
Phone:	+49 6022-240-514
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Email:	andreas.friese@alcon.com
Date Prepared:	July 16, 2020

II. Devices Subject to this 510(k)

Trade Names:	Focus DAILIES, Focus DAILIES Toric, Focus DAILIES Progressives DAILIES AquaComfort Plus, DAILIES AquaComfort Plus FreshTech, DAILIES AquaComfort Plus Toric, DAILIES AquaComfort Plus Multifocal
Common Name:	Soft Contact Lenses
Classification Name:	Soft (Hydrophilic) Contact Lenses
Device Classification:	Class II [21 CFR 886.5925]
Product Code:	LPL, MVN

III. Predicate Device

The 510(k) devices are a modification of the same predicate devices, i.e. Focus DAILIES and DAILIES AquaComfort Plus family (nelfilcon A) soft contact lenses, which are legally commercialized devices in the US per the following most recent US FDA 510(k) clearances: K180669 and K181454.

IV. Device Description

Focus DAILIES and DAILIES AquaComfort Plus are soft contact lenses, intended for the optical correction of refractive error. The lenses are available in spherical, toric and multifocal designs.

The Focus DAILIES and DAILIES AquaComfort Plus lens material is nelfilcon A, a high water, non-ionic hydrophilic lens material consisting of approximately 31% PVA (polyvinyl alcohol partially acetalized with N-formylmethyl acrylamide) and 69% water.

The lens material is considered a Group II high water, non-ionic contact lens material per the 1994 FDA Premarket Notification (510(k)) guidance document for daily wear contact lenses. The lens material further contains non-functionalized high molecular weight PVA (for Focus DAILIES lenses) and/or ultra-high molecular weight PVA (for Dailies AquaComfort Plus lenses) and the color additive phthalocyanine blue to create a light blue edge to edge tint (Visitint™) to make the lenses easier to see when handling.

Focus DAILIES and DAILIES AquaComfort Plus soft contact lenses are supplied sterile. The lenses immersed in buffered saline solution are packaged in individual foil-blister-packs primary packaging system and are terminally sterilized in a validated autoclave (moist heat, steam under pressure).

The foil-blister pack primary packaging system consists of an injection molded polypropylene blister shell sealed with a polyester coated aluminum foil lidding material top.

The lenses are supplied in strips of five foil sealed blister packs each containing approximately 0.65 ml (DAILIES AquaComfort Plus products) and/or 0.85 ml (Focus DAILIES products) phosphate-acetate buffered saline solution. The packaging saline may contain up to 0.05% Poloxamer 108. For DAILIES AquaComfort Plus lenses the package saline additionally contains the comfort additives hydroxypropylmethyl cellulose (HPMC) and polyethylene glycol 400 (PEG 400). Sealed blister strips are provided in secondary packaging carton boxes containing 5, 30 or 90 lenses each.

V. Indications for Use

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

Focus DAILIES and Focus DAILIES Toric (nelfilcon A) One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with nondiseased eyes.

Focus DAILIES Progressives (nelfilcon A) One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or presbyopia in not-aphakic persons with non-diseased eyes who 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.

The lenses are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

DAILIES AquaComfort Plus and DAILIES AquaComfort Plus FreshTech (nelfilcon A) One-Day Contact Lenses are indicated for daily wear 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 AquaComfort Plus Toric (nelfilcon A) One-Day Contact Lenses are indicated for daily 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 AquaComfort Plus Multifocal (nelfilcon A) One-Day Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or presbyopia 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.

All DAILIES AquaComfort Plus (nelfilcon A) One-Day Contact Lenses are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

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 Focus DAILIES and DAILIES AquaComfort Plus 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		
510(k) Number	K180669 and K181454	To be assigned
Product Name(s)	Focus DAILIES, Focus DAILIES Toric, Focus DAILIES Progressives, DAILIES AquaComfort Plus, DAILIES AquaComfort Plus FreshTech, DAILIES AquaComfort Plus Toric, DAILIES AquaComfort Plus Multifocal	Same
Device Classification Information	Class II, Soft (Hydrophilic) Contact Lenses, 21 CFR 886.5925	Same
Indications For Use Information		
Intended Use	One-day contact lenses for the optical correction of refractive error. Single use, daily disposable wear.	Same
Technology Information		
Lens Material	nelfilcon A	Same
Material Classification	FDA Group II (>50% H_2O, nonionic)	Same
Water Content	69%	Same
Visibility Tint	Light blue	Same
Manufacturing Method	Lightstream Technology: Full mold cast	Same
Lens Designs	Spherical, aspherical, toric, multifocal	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: • Constantia-Pirk Folien • Huhtamaki	Multi-layer laminate structure polyester-coated aluminum foil lidding supplied by: • Constantia-Pirk Folien • Huhtamaki • Containers Printers
Package Storage / Saline Solution	Phosphate-acetate buffered saline (with PEG and HPMC additives for DAILIES AquaComfort Plus products) and up to 0.05% Poloxamer 108	Same
Performance Specifications including any Testing		
Refractive Index	1.38	Same
Light Transmittance	≥ 92%T	Same
Oxygen Permeability (Dk)	26	Same
Elastic Modulus	0.9 MPa	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. The non-clinical testing was conducted as described in the following standards.

Standard Identifier	Standard Title	Version	FDA Recognition Number
ISO 10993-1	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process	2018	2-258
ISO 10993-5	Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	2009	2-245
ISO 10993-10	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	2010	2-174
ISO 10993-11	Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity	2017	2-255

Clinical Testing

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