April 10, 2018

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

Re: K180398
Trade/Device Name: Focus DAILIES / Focus DAILIES Toric / Focus DAILIES Progressives, DAILIES AquaComfort Plus (DACP) / DACP Toric / DACP Multifocal, FreshLook One-Day, DAILIES Total1, DAILIES Total1 Multifocal
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: February 12, 2018
Received: February 13, 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. 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.

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.

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 yours,

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)*
K180398

Device Name
Focus DAILIES, Focus DAILIES Toric, Focus DAILIES Progressives

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.

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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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)*
K180398

Device Name
DAILIES AquaComfort Plus, DAILIES AquaComfort Plus Toric, DAILIES AquaComfort Plus Multifocal

Indications for Use *(Describe)*

DAILIES AquaComfort Plus (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)

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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)*
K180398

Device Name
FreshLook One-Day

Indications for Use *(Describe)*
FreshLook spherical (nelfilcon A) One Day Color Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes. The FreshLook spherical (nelfilcon A) One Day Color Contact Lenses also act to enhance or alter the apparent color of the eye.

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.

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)

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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)*
K180398

Device Name
DAILIES TOTAL1, DAILIES TOTAL1 Multifocal

Indications for Use *(Describe)*

DAILIES TOTAL1 (delefilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism.

DAILIES TOTAL1 (delefilcon A) multifocal soft contact lenses are indicated 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 .

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.

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)

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510(k) SUMMARY K180398

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

I. Submitter of 510(k)

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Date Prepared: February 12, 2018

II. Devices Subject to this 510(k)

Trade Names:	***DAILIES AquaComfort Plus soft contact lenses:*** DAILIES AquaComfort Plus, DAILIES AquaComfort Plus Toric, DAILIES AquaComfort Plus Multifocal ***Focus DAILIES soft contact lenses:*** Focus DAILIES, Focus DAILIES Toric, Focus DAILIES Progressives ***DAILIES Total1 soft contact lenses:*** DAILIES Total1, DAILIES Total1 Multifocal ***FreshLook One-Day soft contact lenses:*** FreshLook One-Day
Common Name:	Soft Contact Lenses
Classification Name:	Soft (Hydrophilic) Contact Lens

Device Classification:	Class II [21 CFR 886.5925]
Product Code:	LPL, MVN

III. Predicate Device

The 510(k) devices are modifications of the same predicate devices, i.e. the currently legally commercialized devices in the US per the following most recent US FDA 510(k) clearances: K172066 (DAILIES AquaComfort Plus products), K153643 (Focus DAILIES products), K050213 (FreshLook One-Day product) and K113168 (DAILIES Total1 products).

IV. Device Description

Focus DAILIES, DAILIES AquaComfort Plus, FreshLook One-Day and DAILIES Total1 are soft contact lenses intended for the optical correction of refractive error. They are available in spherical, toric and multifocal designs as applicable:

Spherical lenses: Focus DAILIES, DAILIES AquaComfort Plus, FreshLook One-Day and DAILIES Total1
Toric lenses: Focus DAILIES Toric and DAILIES AquaComfort Plus Toric
Multifocal lenses: Focus DAILIES Progressives, DAILIES AquaComfort Plus Multifocal and DAILIES Total1 Multifocal

The lens material of Focus DAILIES, DAILIES AquaComfort Plus, and FreshLook One-Day products 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. For Focus DAILIES and DAILIES AquaComfort Plus products the lens material further contains non-functionalized PVA (high- and/or ultra-high molecular weight PVA) 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. Additionally, lenses may be printed with inks containing one or more of the following color additives: phthalocyanine blue (CFR 74.3045) and phthalocyanine green (CFR 73.3124). FreshLook One-Day color contact lenses are printed with an intermittent coating containing the following pigments (either alone or in combination): iron oxides, titanium dioxide, Cu-phthalocyanine blue, chromium oxide and phthalocyanine green. All pigments are approved color additives for use in contact lenses.

DAILIES Total1 products are made from a silicone hydrogel material containing approximately 33% water and 67% delefilcon A. Delefilcon A soft contact lenses are surface coated with hydrophilic components. The lenses contain a color additive (copper phthalocyanine blue) to assist handling (handling tint). In addition, lenses

contain 1,2-Dimyristoyl-sn-glycero-3-phosphocholine which is considered a 'comfort agent' to improve lens wearing comfort by physical mode of action (water binding and lens lubricating effect).

Focus DAILIES, DAILIES AquaComfort Plus, FreshLook One-Day and DAILIES Total1 products 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 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 (for DAILIES AquaComfort Plus and DAILIES Total1) and/or approximately 0.85 ml (for Focus DAILIES and FreshLook One-Day) of phosphate-acetate buffered saline solution. The packaging saline may contain up to 0.05% Poloxamer 108. The package saline of DAILIES AquaComfort Plus family lenses 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 (Focus DAILIES, DAILIES AquaComfort Plus, DAILIES Total1) and/or 10 lenses each (FreshLook One-Day), respectively.

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:

DAILIES AquaComfort Plus:

DAILIES AquaComfort Plus (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.

Focus DAILIES:

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.

FreshLook One-Day:

FreshLook spherical (nelfilcon A) One Day Color Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes. The FreshLook spherical (nelfilcon A) One Day Color Contact Lenses also act to enhance or alter the apparent color of the eye.

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 Total1:

DAILIES TOTAL1 (delefilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism.

DAILIES TOTAL1 (delefilcon A) multifocal soft contact lenses are indicated 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 .

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.

VI. Comparison of Technological Characteristics with the Predicate Device

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 Devices	Modified Devices
Administrative / Regulatory Information		
510(k) Number	K172066 (DAILIES AquaComfort Plus) K153643 (Focus DAILIES) K050213 (FreshLook One-Day) K113168 (DAILIES Total1)	To be assigned
Product Name	DAILIES AquaComfort Plus, DAILIES AquaComfort Plus Toric, DAILIES AquaComfort Plus Multifocal Focus DAILIES, Focus DAILIES Toric, Focus DAILIES Progressives FreshLook One-Day DAILIES Total1, DAILIES Total1 Multifocal	Same
Device Classification Information	Class II, Daily Wear Soft (Hydrophilic) Contact Lenses, 21 CFR 886.5925 (b) (1)	Same
Indications For Use Information		
Intended Use	One-day contact lenses for the optical correction of vision. Single use, daily disposable wear.	Same

Table 1: Substantial Equivalence Comparison

Element of Comparison	Predicate Devices	Modified Devices
Technology Information		
Lens Material	nelfilcon A (Focus DAILIES, DAILIES AquaComfort Plus and FreshLook One-Day) delefilcon A (DAILIES Total1)	Same
Water Content	69% (Focus DAILIES, DAILIES AquaComfort Plus and FreshLook One-Day) 33% (DAILIES Total1)	Same
Visibility Tint	Focus DAILIES, DAILIES AquaComfort Plus and DAILIES Total1: Light blue (copper phthalo-cyanine blue) FreshLook One-Day: No tint	Same
Manufacturing Method	Lightstream Technology: Full mold cast	Same
Lens Designs	Spherical, toric, multifocal (Focus DAILIES and DAILIES AquaComfort Plus) Spherical (FreshLook One-Day) Spherical, multifocal (DAILIES Total1)	Same
Sterilization	Steam sterilization, validated autoclave	Same
Primary Packaging System in General	Foil blister pack container system: Polypropylene blister shell sealed with a polyester coated aluminum foil lidding	Same

Table 1: Substantial Equivalence Comparison

Element of Comparison	Predicate Devices	Modified Devices
Primary Packaging Blister Shell	Injection-molded polypropylene blister shell made from Flint Hills Resources P4C5N-046 polypropylene or Formosa 4142T polypropylene	Same
Primary Packaging Foil Lidding	Multi-layer laminate structure polyester-coated aluminum foil lidding supplied by Constantia-Hueck Folien Current 2017 grade as supplied by Constantia-Hueck Folien	Multi-layer laminate structure polyester-coated aluminum foil lidding supplied by Constantia-Hueck Folien Modified 2018 grades as supplied by Constantia-Hueck Folien
Package Storage / Saline Solution	Nelfilcon A products: Phosphate-acetate buffered saline with up to 0.05% Poloxamer 108. Additionally contains PEG and HPMC (for DAILIES AquaComfort Plus) Delefilcon A products: Phosphate buffered saline solution with approximately 0.3% of polymeric wetting agents consisting of copolymers of polyamidoamine and poly (acrylamide-acrylic acid)	Same

Table 1: Substantial Equivalence Comparison

Element of Comparison	Predicate Devices	Modified Devices
Performance Specifications including any Testing		
Refractive Index	Nelfilcon A products: 1.38 Delefilcon A products: 1.42	Same
Light Transmittance	Nelfilcon A products: ≥92%T (≥88%T for FreshLook One-Day) Delefilcon A products: ≥93%T	Same
Oxygen Permeability (Dk)	Nelfilcon A products: 26 Delefilcon A products: 140	Same
Elastic Modulus	Nelfilcon A products: 0.9 MPa Delefilcon A products: 0.7 MPa	Same
Biocompatibility	Biocompatible as confirmed by appropriate biocompatibility testing	Same
Shelf-life	Up to 60 months as confirmed by shelf-life stability testing (Focus DAILIES and DAILIES AquaComfort Plus) Up to 48 months as confirmed by shelf-life stability testing (FreshLook One-Day, DAILIES Total1)	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* and applicable ISO standards for contact lenses. The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility Testing

Test results from a series of *in vitro* and *in vivo* biocompatibility evaluations, including cytotoxicity, ocular irritation and systemic toxicity testing, confirm that the minor device modification does not negatively impact the safety of the devices and that the modified devices are non-toxic and biocompatible.

All biocompatibility testing was conducted in accordance with the GLP regulation (21 CFR Part 58) and relevant ISO 10993 series biocompatibility standards.

Stability Testing

Successful stability testing supports the labeled expiration date for the modified devices.

Clinical Testing

Based on the great similarity of the modified devices to the predicate devices and successful results from nonclinical testing, clinical testing was not required to establish substantial equivalence.

VIII. Conclusions

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