December 11, 2018

Alcon Laboratories, Inc.
Alicia Plesnarski
Director, Global Regulatory Affairs, Vision Care
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K182902
Trade/Device Name: Precision1™
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: October 16, 2018
Received: October 16, 2018

Dear Alicia Plesnarski:

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 yours,

J. Angelo Green

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)*
K182902

Device Name
Precision1

Indications for Use *(Describe)*

Precision1 (verofilcon A) Spherical and Precision1 Asphere (verofilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

Precision1 for Astigmatism (verofilcon A) toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and 6.00 diopters (D) or less of astigmatism.

Precision1 Multifocal (verofilcon A) multifocal soft contact lenses are indicated 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 have up to approximately 1.50 diopters of astigmatism.

Precision1 Multifocal Toric (verofilcon A) soft contact lenses are indicated 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 6.00 diopters (D) of astigmatism.

The lenses are to be prescribed for single use, daily disposable wear, as recommended by the eye care professional. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K182902

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:	Alicia M. Plesnarski, RAC
Phone:	678 415-3924
Fax:	N/A
Email:	alicia.plesnarski@alcon.com
Back up Contact Person:	Sherri Lakota
Phone:	817 615-5472
Fax:	817 302-4574
Email:	sherri.lakota@alcon.com
Date Prepared:	05 December 2018

II. Devices Subject to this 510(k)

Trade name (brand):	Precision1™
Common name:	(verofilcon A) One-Day Contact Lens
Classification name:	Soft (hydrophilic) Contact Lens
Device classification:	21 CFR 886.5925 (b) (1)
Product code:	LPL; MVN

III. Predicate Device

The predicate device is the Alcon® DAILIES TOTAL1® (delefilcon A) soft contact lens. Delefilcon A represents a Group V silicone hydrogel contact lens material ('enhanced oxygen permeable materials') according to ISO 18369-1:2006/Amd.1:2009 *Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labelling specifications*. The 2017 revision of the standard further classifies silicone hydrogels into sub-

groups. According to ISO 18369-1:2017 the delefilcon A silicone hydrogel material is in the soft contact lens material group classification as follows:

Group Suffix	Hydrogel Material	Description
5C	Low water subgroup	A subgroup of Group 5 which contains less than 50 % water and no ionic monomer or oligomer at pH 6 to pH 8

The predicate device has US FDA Premarket Notification 510(k) clearance for daily disposable wear (K113168, March 30, 2012).

IV. Device Description

The subject device, Precision1™ (verofilcon A) soft contact lenses, are made from a silicone containing hydrogel lens material that is approximately 51% water and 49% verofilcon A. The color additive Reactive Blue 247 is added to the lens material to create a light blue edge-to-edge color to make it easier to see when handling. In addition, lenses contain a benzotriazole UV-absorbing monomer to block UVA and UVB radiation.

Verofilcon A represents a Group V silicone hydrogel contact lens material ('enhanced oxygen permeable materials') according to ISO 18369-1:2006/Amd.1:2009 *Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labelling specifications*. The 2017 revision of the standard further classifies silicone hydrogels into sub-groups. According to ISO 18369-1:2017 the verofilcon A silicone hydrogel material is in the soft contact lens material group classification as follows:

Group Suffix	Hydrogel Material	Description
5B	High water subgroup	A subgroup of Group 5 which contains more than 50 % water and no ionic monomer or oligomer at pH 6 to pH 8

Verofilcon A lens designs include spherical, asphere, toric, multifocal and multifocal toric lenses in the following parameter ranges:

- 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
  (Example: 0.09 mm for -3.00 D spherical)

Lenses have the following properties:

- Refractive index: 1.4 (hydrated)

- Water content : 51% by weight in normal saline
- Oxygen permeability: 90 x 10^{-11} [(cm^2 /sec)(ml O_2 /ml•mmHg)] measured at 35 °C (intrinsic Dk-Coulometric method)
- Light transmittance: > 90 %
- UV Transmittance: The transmittance characteristics are less than 1% in the UVB range of 280 nm to 315 nm and less than 10% in the UVA range of 316 to 380 nm for the entire power range.

Verofilcon A contact lenses are supplied sterile in sealed blister packs containing isotonic phosphate buffered saline solution (PBS) with approximately 0.3% of polymeric wetting agents consisting of copolymers of polyamidoamine and poly (acrylamide-acrylic) acid. The compatibility and package integrity of the blister pack packaging system have 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, 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).

V. Indications for Use

Precision1 (verofilcon A) spherical and Precision1 Asphere (verofilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

Precision1 for Astigmatism (verofilcon A) toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and 6.00 diopters (D) or less of astigmatism.

Precision1 Multifocal (verofilcon A) multifocal soft contact lenses are indicated 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 have up to approximately 1.50 diopters of astigmatism.

Precision1 Multifocal Toric (verofilcon A) soft contact lenses are indicated 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 6.00 diopters (D) of astigmatism.

The lenses are to be prescribed for single use, daily disposable wear, as recommended by the eye care professional. 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

Table 1 provides a side-by-side comparison of the device as compared to the predicate device in terms of intended use and technological information.

Table 1. Substantial Equivalence Comparison

	Predicate Device	Subject Device
Trade Name (brand)	DAILIES TOTAL1®	Precision1™
Submission Number	K113168	K182902
Device Classification Name	Daily Wear Soft Contact Lens 21 CFR 886.5925 (b)(1)	Same
Intended Use	Vision correction	Same
Mode of Action	When hydrated and placed on the cornea, lenses act as a refracting medium to focus light rays on the retina.	When hydrated and placed on the cornea, lenses act as a refracting medium to focus light rays on the retina. The lenses contain a UV blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye.*
Wearing Schedule	Daily disposable wear	Same
Replacement Schedule	Daily	Same
Material Classification	Group 5C, low water silicone hydrogel according to ISO 18369-1:2017	Group 5B, high water silicone hydrogel according to ISO 18369-1:2017
Lens Material	Delefilcon A	Verofilcon A
Surface Treatment	In-process Coating (IPC)	Same
Manufacturing Method	LightStream (molded)	DSM-FLEX (molded)
Visibility Tint	Light blue	Same

Table 1. Substantial Equivalence Comparison

	Predicate Device	Subject Device
Lens Designs	Spherical, toric, multifocal, multifocal toric	Spherical, asphere, toric, multifocal, multifocal toric
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
Water Content	33%	51%
Refractive Index	1.4	Same
Oxygen Permeability	140 barrer units**	90 barrer units
Sterilization	Steam sterilization, validated autoclave	Same
Packaging	Tear drop blister pack	Same
Package Storage Saline Solution	Phosphate buffered saline (PBS) with polymeric wetting agents	Same

*UV absorbers are commonly found in numerous US legally commercialized contact lenses (examples K151918; K100349; K131378)

**1 barrer = x 10^{-11} (cm^2/sec)(ml O_2 /ml x mm Hg)

Verofilcon A soft contact lenses are equivalent to the predicate lens and similar to other daily disposable wear soft contact lenses in terms of technological characteristics and intended use.

Any differences which may exist between the subject device (verofilcon A soft contact lenses) and the predicate device or other daily disposable, silicone hydrogel soft contact lenses do not adversely affect the safety and effectiveness of the subject device.

VII. Performance Data

A series of nonclinical tests and a clinical study were performed to characterize and demonstrate the substantial equivalence of verofilcon A contact lenses to the predicate device. All testing was conducted in accordance with the May 1994 FDA guideline titled *Premarket Notification 510(k) Guidance Document for Class II Contact Lenses* and ISO standards, as applicable. In addition, nonclinical biocompatibility testing was conducted in accordance with the GLP regulation (21 CFR Part 58).

Biocompatibility Testing

As listed below, a series of *in vitro* and *in vivo* biocompatibility evaluations, including cytotoxicity, ocular irritation, sensitization, systemic and genotoxicity toxicity testing, confirm that verofilcon A contact lenses are non-toxic and biocompatible.

- Cytotoxicity Study Using the ISO Direct Contact Method
- Cytotoxicity Study Using the ISO Elution Method
- Cytotoxicity Study Using the ISO Modified Method Elution Method
- Cytotoxicity Study Using the Cell Growth Inhibition Method
- 22 Day Contact Lens Study in Rabbits
- ISO Ocular Irritation Study in Rabbits
- ISO Acute Systemic Toxicity Study in Mice
- Guinea Pig Maximization Sensitization Study
- Bacterial Reverse Mutation Study
- In Vitro Chromosomal Aberration Study in Chinese Hamster Ovary Cell

Biocompatibility testing was conducted in accordance with the US Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies regulation (21 CFR Part 58) and relevant ISO 10993 series of biocompatibility standards.

Physical-Chemical Testing

The following nonclinical bench testing, conducted using GxP conditions and, where applicable ISO 18369-2, -3, -4 standards, established the physicochemical properties of verofilcon A contact lenses:

- Refractive Index
- Oxygen Permeability
- Ion Permeability
- Mechanical Properties
- Wetting Contact Angle
- Transmittance Properties (luminous, light, UV class)
- Percent Water Content
- Residuals and Extractables
- Lens Parameters (BCE, DIA, PWR, CT)
- Package Saline Properties (pH and osmolality)

Solution Compatibility Testing

Verofilcon A contact lenses are for single use, daily disposable wear only. Although for daily disposable wear no lens care products are needed (lenses disposed of after each daily wearing period), occasional use of contact lens saline solutions and/or rewetting drops may occur. Therefore, compatibility of verofilcon A contact lenses with preserved or unpreserved commercial contact lens saline and rewetting drops was confirmed following the methodology described in ISO 11981:

- Systane® Preservative-Free Lubricant Eye Drops
- Sensitive Eyes® Rewetting Drops
- Sensitive Eyes® Plus Saline Solution
- Systane® Contacts Lubricant Eye Drops
- Blink-N-Clean® Eye drops (formerly known as COMPLETE Lubricating and Rewetting Drops)

Verofilcon A contact lenses were also analyzed for uptake and release of preservatives found in various lens care products. Uptake and release profiles were comparable to the control lenses tested:

- Polyquad (PQ) containing lens drop (i.e., Systane® Contacts Lubricant Eye Drops)
- Polyhexamethylene biguanide (PHMB) containing lens drop (i.e., Blink-N-Clean® Eye drops formerly known as COMPLETE Lubricating and Rewetting Drops)

Sterilization and Stability Testing

Verofilcon A contact lenses in saline solution are provided sterile in sealed blister packs. Results of an ongoing stability study demonstrate that package lenses remain sterile and stable for the labeled expiration date.

The results of all nonclinical testing demonstrate:

- The lens material, lens extracts and package saline of the device are non-toxic, non-irritating and non-sensitizing.
- Lens physical and material properties of the device are consistent with industry-marketed lenses and equivalent to the predicate lens.
- Like the predicate device, the device is compatible with commonly available contact lens saline solutions and rewetting drops.
- Successful stability testing supports the labeled expiration date for the device.

Clinical Performance Testing

A three-month clinical study, conducted according to the May 1994 FDA 510(k) contact lens guidance document for a new contact lens material and ISO 11980, assessed the safety and performance of Precision1™ (verofilcon A) soft contact lenses for single use, daily disposable wear as compared to a predicate control lens (2:1 ratio test to control). Product safety was assessed based on adverse events, device deficiencies and biomicroscopy findings.

Six (6) study sites in the US enrolled a total of one hundred and seven (107) subjects in this prospective, randomized, stratified (by corneal curvature radius), controlled, double-masked, parallel group study. Of the 107 subjects (214 eyes) enrolled into the study, 105 subjects completed the study. The study evaluated 69 verofilcon A (test) subjects and 36 delefilcon A (control) subjects. Contact lenses were worn bilaterally in a daily wear, daily disposable modality for approximately 3 months each. The primary effectiveness endpoint was logMAR VA at distance.

Additional endpoints include refraction, keratometry, lens fit, surface characteristics and subjective ratings of vision, comfort and handling.

The study results showed similar clinical performance between the test verofilcon A and control delefilcon A lenses in the clinically relevant areas of vision, comfort, fit, handling and health when worn on a daily disposable wear basis.

The clinical study demonstrated the substantial equivalence of the subject device with the predicate, control lens.

Risk and Benefits
The risks of the subject device are the same as those normally attributed to the wearing of silicone hydrogel contact lenses in a single use, daily wear basis. The benefits to the patient are the same as those for other silicone hydrogel contact lenses.

VIII. Conclusions

Verofilcon A soft contact lenses are substantially equivalent to the predicate lens and similar to other daily disposable wear soft contact lenses in terms of technological characteristics and intended use.

Any differences which may exist between the subject device (verofilcon A soft contact lenses) and the predicate device or other daily disposable, silicone hydrogel soft contact lenses do not adversely affect the safety and effectiveness of the subject device.