December 28, 2021

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

Re: K212806
Trade/Device Name: Alcon™, Alcon™ for Astigmatism, Alcon™ Multifocal, Alcon™ Multifocal Toric (serafilcon A) soft contact lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: November 19, 2021
Received: November 22, 2021

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/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 titled, "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,

J. Angelo Green, Ph.D.
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)*
K212806

Device Name

Alcon, Alcon for Astigmatism, Alcon Multifocal, Alcon Multifocal Toric (serafilcon A) soft contact lenses

Indications for Use *(Describe)*

Alcon (serafilcon 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 with up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

Alcon for Astigmatism (serafilcon 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 who may have up to 6.00 diopters (D) of astigmatism.

Alcon Multifocal (serafilcon 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 approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

Alcon Multifocal Toric (serafilcon 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 daily wear with removal for disposal, or cleaning and disinfection (chemical not heat) prior to reinsertion, as recommended by the eye care professional. Lenses should be discarded and replaced with a new pair each week, or more often, if recommended by the eye care professional.

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.

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:	Alicia M. Plesnarski, RAC
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Date Prepared:	December 22, 2021

II. Devices Subject to this 510(k)

Trade name (brand):

Alcon™
Alcon™ for Astigmatism
Alcon™ Multifocal
Alcon™ Multifocal Toric

Common name: (serafilcon A) soft 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 CooperVision Biofinity (comfilcon A) soft contact lens. Comfilcon A represents a Group 5C silicone hydrogel contact lens material ('enhanced oxygen permeable materials') according to ISO 18369-1:2017, *Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labelling specifications*, 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 wear (K052560, December 6, 2005).

IV. Device Description

The subject device is made from a silicone containing hydrogel lens material that is approximately 55% water and 45% serafilcon A. The color additive Reactive Blue 247 is added to the lens material to create a light blue-green edge-to-edge color to make it easier to see when handling. In addition, lenses contain two benzotriazole monomers to block UVA and UVB radiation, and additionally, reduce transmittance in the range of 380 nm to 450 nm.

Serafilcon A represents a Group 5B silicone hydrogel contact lens material ('enhanced oxygen permeable materials') according to ISO 18369-1:2017, *Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labelling specifications,* 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

Serafilcon A lens designs include spherical, 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: 0.08 mm for -3.00 D spherical)
- Cylinder Power (toric) Range: -0.25 D to -10.00 D
- Cylinder Axis (toric) Range: 001 to 180°
- ADD Power (multifocal) Range: LO, MED, HI

Lenses have the following properties:

- Refractive index: 1.40 (hydrated)
- Water content : 55% by weight in normal saline
- Oxygen permeability: 119×10^{-11} $[(cm^2/sec)(ml\ O_2/ml \bullet mmHg)]$ measured at 35 °C (normalized Dk-Polarographic method)
- Light transmittance: ≥85%
- 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.

Serafilcon A contact lenses are supplied sterile in sealed blister packs containing isotonic phosphate buffered saline solution (PBS) with polymeric wetting agents. The compatibility and package integrity of the blister pack packaging system have been demonstrated and successfully

used for other Alcon marketed contact lens products, and packaged lenses are effectively steam sterilized in a validated autoclave. Blister pack containers are labeled with variable information such as 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

Alcon™ (serafilcon 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 with up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

Alcon™ for Astigmatism (serafilcon 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 who may have up to 6.00 diopters (D) or less of astigmatism.

Alcon™ Multifocal (serafilcon 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 have up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.

Alcon™ Multifocal Toric (serafilcon 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 daily wear with removal for disposal, or cleaning and disinfection (chemical, not heat) prior to reinsertion, as recommended by the eye care professional. Lenses should be discarded and replaced with a new pair each week, or more often, if recommended by the eye care professional.

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 (Coopervision)	**Subject Device (Alcon)**
Trade Name (brand)	Biofinity	Alcon
Submission Number	510(k) K052560	510(k) K212806
Device Classification Name	Daily Wear Soft Contact Lens 21 CFR 886.5925 (b)(1)	Same
Intended Use	Vision correction	Same
Wearing Modality	Daily wear	Same
Replacement Schedule	One month	One week
Material Classification ISO 18369-1:2017	Group 5C, low water silicone hydrogel	Group 5B, high water silicone hydrogel
Lens Material	Comfilcon A	Serafilcon A
Visibility Tint	Light blue	Light blue-green
UV/UV vis absorbing monomers	No	Yes*
Manufacturing Method	Cast molded	Cast molded (DSMFLEX)
Lens Designs	Spherical, asphere, toric, multifocal, multifocal toric	Spherical, toric, multifocal, multifocal toric

Table 1. Substantial Equivalence Comparison

	Predicate Device (Coopervision)	Subject Device (Alcon)
Power Range	+20.00 to -20.00 D	Same
Base Curve Range	8.0 to 9.5 mm	8.0 to 9.2 mm
Diameter Range	13.5 to 15.0 mm	13.0 to 15.0 mm
Cylinder Power (toric):	-0.25 to -10.00 D	Same
ADD Power (multifocal)	+0.50 to +3.00 D	LO, MED, HI
Water Content	48%	55%
Refractive Index	1.4	Same
Oxygen Permeability	128** (Coulometric method)	119 (Polarographic method)
Sterilization	Steam sterilization, validated autoclave	Same
Packaging	Cartons containing sealed blister packs	Same
Package Storage Saline Solution	Isotonic saline	Phosphate buffered saline (PBS) with additives

*UV absorbers are commonly found in numerous US legally commercialized contact lenses (examples K151918; K100349; K131378; K182782; K210436)

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

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

Any differences which may exist between the subject device (serafilcon A soft contact lenses) and the predicate device or other daily wear, 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 demonstrate the substantial equivalence of serafilcon 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/toxicity, sensitization, systemic and genotoxicity testing, confirm that serafilcon A contact lenses are non-toxic and biocompatible.

- Cytotoxicity Studies (lens, lens extracts and package saline)
- Ocular Irritation / Toxicity (Ocular) in Rabbits
    - Lens wear study in rabbits per ISO 9394 (lens)
    - Primary ocular irritation studies per ISO 10993-10 (lens extracts and package saline
- Sensitization Studies (lens extracts and package saline)
- Acute Systemic Toxicity Study in Mice (lens extracts)
- Genotoxicity Studies (lens extracts and package saline)

The primary packaging materials used for serafilcon A lenses are the same as those used for other Alcon contact lenses with FDA 510(k) clearance (K113168, K180398, K180669, K210436), therefore existing biocompatibility data for the packaging materials applies.

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 serafilcon A contact lenses:

- Refractive Index
- Oxygen Permeability
- Ion Permeability
- Mechanical Properties
- Wetting Contact Angle
- Transmittance Properties
- Percent Water Content
- Residuals and Extractables
- Lens Parameters
- Package Saline Properties (pH and osmolality)

Solution Compatibility Testing

Serafilcon A contact lenses are for daily wear use with daily removal for cleaning and disinfection and one-week replacement. Therefore, the compatibility of serafilcon A contact lenses with commonly available cleaning and disinfection solutions (3% hydrogen peroxide and MPDS), and preserved or unpreserved commercial contact lens saline and rewetting drops, was confirmed following the methodology described in ISO 11981, *Ophthalmic optics – Contact lenses and contact lens care products – Determination of physical compatibility of contact lens care products with contact lenses*.

Serafilcon A contact lenses were also analyzed for uptake and release of preservatives found in various lens care products. Testing was conducted according to ISO 11986, *Ophthalmic optics – Contact lenses and contact lens care products – Determination of preservative uptake and release.* Uptake and release profiles of serafilcon A contact lenses for Polyquad (PQ), Aldox, Polyhexamethylene biguanide (PHMB) and Alexidine were comparable to the control lenses tested.

Sterilization and Stability Testing

Serafilcon 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 non-clinical 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 cleaning and disinfecting solutions, 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) daily wear contact lens guidance document for a new contact lens material and ISO 11980, *Ophthalmic optics-Contact lenses and contact lens care products – Guidance for clinical investigations*, assessed the safety and performance of serafilcon A soft contact lenses for daily 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.

Eight (8) study sites in the US enrolled a total of one hundred and twenty (120) subjects in this prospective, randomized, stratified (by corneal curvature radius), controlled, double-masked, parallel group study. One subject was a screen failure. Of the 120 subjects (240 eyes) enrolled into the study, 119 subjects were randomized, exposed to the study lenses and 110 subjects completed the study. The study evaluated 78 serafilcon A (test) subjects and 41 comfilcon A (control) subjects. Contact lenses were worn bilaterally in a daily wear modality for approximately 3 months each. The test lenses were replaced weekly and the control lenses were replaced monthly. The primary effectiveness endpoint was study lens visual acuity at distance. The demographic characteristics for all enrolled subjects were similar between the serafilcon A and comfilcon A groups. The majority of the subjects in both groups were female (76.5%), predominantly White, and most were not of Hispanic or Latino ethnicity. The overall mean age of the subjects was 32.4 years.

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

The study results showed similar clinical performance between the test and control lenses in the clinically relevant areas of vision, comfort, fit, handling and health when worn on a daily 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 on a daily wear basis. The benefits to the patient are the same as those for other silicone hydrogel contact lenses.

VIII. Conclusions

Serafilcon A soft contact lenses are substantially equivalent to the predicate lens and similar to other daily wear soft contact lenses in terms of technological characteristics and intended use. Non-clinical and clinical data demonstrate that the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device.

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