April 20, 2023

Alcon Laboratories, Inc.
Dr. Andreas Friese
Regulatory Project Director
Industriering 1
Grosswallstadt, Bayern 63868
Germany

Re: K230785
Trade/Device Name: Precision1, Precision1 for Astigmatism
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: March 20, 2023
Received: March 22, 2023

Dear Dr. 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. 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,

J Angelo Green -S

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.

Submission Number *(if known)*

K230785

Device Name

Precision1
Precision1 for Astigmatism

Indications for Use *(Describe)*

Precision1 (verofilcon 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 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.

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.

K230785

510(k) Summary

Prepared on: 2023-04-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Alcon Laboratories, Inc.
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Correspondent Contact	Dr. Andreas Friese
Correspondent Contact Email	andreas.friese@alcon.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Precision1, Precision1 for Astigmatism
Common Name	Soft (hydrophilic) contact lens
Classification Name	Soft (hydrophilic) contact lens
Regulation Number	886.5925
Product Code	LPL, MVN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K182902	Precision1	LPL

Device Description Summary

21 CFR 807.92(a)(4)

Precision1 (verofilcon A) soft contact lenses are currently available in a spherical and a toric lens design.
Precision1 (verofilcon 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 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 nondiseased eyes and 6.00 diopters (D) or less of astigmatism.
Precision1 (verofilcon A) soft contact lenses are supplied sterile, immersed in buffered saline solution and packaged in individual foil-blister packs, which are terminally sterilized in a validated autoclave (moist heat, steam under pressure).
The foil-blister pack system consists of a polypropylene (PP) blister shell sealed with a coated

aluminum foil lidding. The blister packs are packaged into carton boxes available in different pack sizes.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Precision1 (verofilcon 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 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.

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the modified device remain the same as for the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The 510(k) devices are a modification of the same predicate devices, i.e. Precision1 and Precision1 for Astigmatism (verofilcon A) soft contact lenses, which are legally commercialized devices in the US under 510(k) K182902.

The proposed device modification involves adding an alternate lidding foil from alternate supplier for primary packaging of Precision1 (verofilcon A) soft contact lens products and extending the product expiration dating from 72 to 84 months.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

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