January 13, 2025

Alcon Laboratories, Inc.
Dr. Andreas Friese
Regulatory Project Director
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K243909
Trade/Device Name: Precision1; Precision1 for Astigmatism; Dailies Total1; Dailies Total1 for Astigmatism; Dailies Total1 Multifocal; Dailies Total1 Multifocal Toric
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: December 18, 2024
Received: December 19, 2024

Dear Dr. 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243909

Device Name

Precision1;
Precision1 for Astigmatism;
Dailies Total1;
Dailies Total1 for Astigmatism;
Dailies Total1 Multifocal;
Dailies Total1 Multifocal Toric

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.

Precision1 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.

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 that does not interfere with visual acuity.

Dailies Total1 Multifocal (delefilcon 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 (D) of astigmatism that does not interfere with visual acuity.

Dailies Total1 for Astigmatism (delefilcon 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 6.00 diopters (D) of astigmatism.

Dailies Total1 Multifocal Toric (delefilcon 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.

Dailies Total1 lenses are to be used for single use, daily disposable wear (less than 24 hours while awake) only. 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)

510(k) #: K243909

510(k) Summary

Prepared on: 2024-12-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Alcon Laboratories, Inc.
Applicant Address	6201 South Freeway Fort Worth TX 76134-2099 United States
Applicant Contact Telephone	+496022240514
Applicant Contact	Dr. Andreas Friese
Applicant Contact Email	andreas.friese@alcon.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Precision1; Precision1 for Astigmatism; Dailies Total1; Dailies Total1 for Astigmatism; Dailies Total1 Multifocal; Dailies Total1 Multifocal Toric
Common Name	Soft (hydrophilic) contact lens
Classification Name	ailies Total1: LPL (Class 2) - Lenses, Soft Contact, Daily Wear; MVN (class2) lens, contact, (disposable)
Regulation Number	886.5925
Product Code(s)	Precision1 and Dailies Total1: LPL (Class 2) - Lenses, Soft Contact, Daily

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233856 (P1) and K	Precision1 / Dailies Total1	LPL; MVN

Device Description Summary

21 CFR 807.92(a)(4)

Precision1 (P1) (verofilcon A lens material) and Dailies Total1 (DT1) (delefilcon A) are soft contact lenses, intended for on-eye use in persons with healthy eyes that need vision correction as determined and fitted by an eye care professional. The lenses are to be used for single use, daily disposable wear (less than 24 hours while awake) only.

Precision1 (verofilcon A) and Dailies Total1 (delefilcon 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.

Precision1 (verofilcon A) soft contact lenses are currently available in a spherical and a toric (for astigmatism) lens design.

Dailies Total1 (delefilcon A) soft contact lenses are available in spherical, multifocal, toric (for astigmatism) and multifocal toric lens designs.

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.

Precision1 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.

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 that does not interfere with visual acuity.

Dailies Total1 Multifocal (delefilcon 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 (D) of astigmatism that does not interfere with visual acuity.

Dailies Total1 for Astigmatism (delefilcon 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 6.00 diopters (D) of astigmatism.

Dailies Total1 Multifocal Toric (delefilcon 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.

Dailies Total1 lenses are to be used for single use, daily disposable wear (less than 24 hours while awake) only. 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)

There are no device modifications related to the proposed change. This change is a manufacturing change for modification of extraction and coating processes within the manufacturing processes of Precision1 and Dailies Total1 contact lenses.

Technological Comparison 21 CFR 807.92(a)(6)

The 510(k) devices are modifications of the same predicate devices, i.e. Precision1 (verofilcon A) family soft contact lenses, which are legally commercialized devices in the US under 510(k) K233856, and Dailies Total1 (delefilcon A) family soft contact lenses, which are legally commercialized devices in the US under 510(k) K232921.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

There are no device modifications related to the proposed change. This change is a manufacturing change for modification of extraction and coating processes within the manufacturing processes of Precision1 and Dailies Total1 contact lenses. Therefore, the change did not require clinical testing to establish safety and effectiveness of the modified devices. Non-clinical bench testing of the devices manufactured via the proposed modified extraction and coating processes for lens optical, dimensional and surface properties as well as extractables and residuals demonstrated that the lenses meet established finished product specifications and are therefore substantially equivalent to the predicate devices, i.e. Precision 1 and DAILIES Total1 contact lenses manufactured via the current established manufacturing processes.