December 29, 2023

Alcon Laboratories, Inc.
Dr. Andreas Friese, Regulatory Project Director
Alcon / CIBA Vision GmbH
Industriering 1
Grosswallstadt, BY 63868
Germany

Re: K233856
Trade/Device Name: Precision1; Precision1 for Astigmatism; TOTAL30; TOTAL30 for Astigmatism; TOTAL30 Multifocal
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: November 30, 2023
Received: December 5, 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 (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.

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)*

K233856

Device Name

Precision1;
Precision1 for Astigmatism;
TOTAL30;
TOTAL30 for Astigmatism;
TOTAL30 Multifocal

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.

TOTAL30 (lehfilcon 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.

TOTAL30 for Astigmatism (lehfilcon A) toric soft contact lenses are indicated for the optical correction ofrefractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to 6.00 diopters (D) of astigmatism.

TOTAL30 Multifocal (lehfilcon 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.

TOTAL30 lenses are to be prescribed for daily wear, with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, or disposal, as recommended by the eye care professional. Lenses should be discarded and replaced with a new pair each month, 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

Prepared on: 2023-12-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Alcon Laboratories, Inc.
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Precision1; Precision1 for Astigmatism; TOTAL30; TOTAL30 for Astigmatism; TOTAL30 Multifocal
Common Name	Soft (hydrophilic) contact lens
Classification Name	Lenses, Soft Contact, Daily Wear
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, K230785, K210436	Precision1, TOTAL30	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) 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.

Lehfilcon A soft contact lenses are available in a spherical design (for correction of vision in persons with myopia or hyperopia), toric design (for correction of myopia or hyperopia, with astigmatism) and multifocal design (for correction of presbyopia, with or without myopia or hyperopia) in a range of powers and parameters.

Lehfilcon A lenses immersed in package saline and provided sterile in sealed blister packages are fully functioning (i.e., ready to use) out of pack (no need for accessories). Lenses in sealed blister packs (primary packaging) are provided in an outer carton (secondary packaging). For daily wear/reuse, products such as commercially available soft contact lens care cleaning and disinfecting solutions, rewetting drops, saline solutions and contact lens cases may be used. Accessories are sold and provided separately from the device.

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.

TOTAL30 (lehfilcon 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.

TOTAL30 for Astigmatism (lehfilcon A) toric soft contact lenses are indicated for the optical correction ofrefractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to 6.00 diopters (D) of astigmatism.

TOTAL30 Multifocal (lehfilcon 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.

TOTAL30 lenses are to be prescribed for daily wear, with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion, or disposal, as recommended by the eye care professional. Lenses should be discarded and replaced with a new pair each month, or more often, if recommended by the eye care professional.

Indications for Use Comparison

21 CFR 807.92(a)(5)

There are no changes in Indications for Use.

Technological Comparison

21 CFR 807.92(a)(6)

There are no proposed device modifications related to this change. This change only affects quality control measures.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

There are no proposed device modifications related to this change. This change only affects quality control measures. Therefore, the change did not require non-clinical and/or clinical testing. The proposed change was supported by risk assessment and/or scientific-technical assessments demonstrating that there are no new or revised risks to these devices and to the safety and efficiency of these devices. The 510(k) devices are the same as the 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, K230785 and TOTAL30, TOTAL30 for Astigmatism and TOTAL30 Multifocal (lehfilcon A) soft contact lenses, which are legally commercialized devices in the US under 510(k) K210436.