February 13, 2026

Alcon Laboratories, Inc.
Andreas Friese
Senior Manager Regulatory Strategy
6201 S. Freeway
Fort Worth, TX 76134-2099

Re: K254052
Trade/Device Name: DAILIES TOTAL1®; DAILIES TOTAL1® Multifocal
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: December 15, 2025
Received: December 17, 2025

Dear 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254052

Please provide the device trade name(s).

DAILIES TOTAL1®;
DAILIES TOTAL1® Multifocal

Please provide your Indications for Use below.

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.

The 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K254052

510(k) Summary

Prepared on: 2026-02-06

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	+49 6022 240514
Applicant Contact	Dr. Andreas Friese
Applicant Contact Email	andreas.friese@alcon.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	DAILIES TOTAL1® ; DAILIES TOTAL1® Multifocal
Common Name	Soft (hydrophilic) contact lens
Classification Name	Lenses, Soft Contact, Daily Wear
Regulation Number	886.5925
Product Code(s)	LPL, MVN (CLASS 2) - LENS, CONTACT, (DISPOSABLE)

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K113168 & K243909	DAILIES TOTAL1®; DAILIES TOTAL1® MULTIFOCAL	LPL
K113168 & K243909	DAILIES TOTAL1®; DAILIES TOTAL1® MULTIFOCAL	MVN

Device Description Summary

21 CFR 807.92(a)(4)

DAILIES TOTAL1® (sphere) and DAILIES TOTAL1® Multifocal are soft contact lenses made from delefilcon A lens material. Delefilcon A is a silicone hydrogel material with a water content of approximately 33% and a water gradient surface treatment. The lenses have a light blue tint that makes them easier to see when handling. When hydrated and placed on the cornea, DAILIES TOTAL1® (delefilcon A) soft contact lenses act as a refracting medium to focus light rays on the retina.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

DAILIES TOTAL1® (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 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.

The 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)

The indications for use of the subject device remain the same as for the predicate device. The predicate device is characterized by its initial/original 510(k) K113168 and its most recent 510(k) K243909 for a manufacturing change.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device and the predicate device are the same contact lens. The subject device differs from the predicate device only in that the lens dimensional specifications have been updated. This update does not alter the lens design, geometry concept, materials, manufacturing process, or performance characteristics. The device technological characteristics remain unchanged as follows:

- Design: Soft hydrophilic contact lenses
- Material: Silicone hydrogel lens material with a water content of approximately 33% and a water gradient surface treatment.
- Chemical composition: Delefilcon A lens material including a light blue tint that makes the lenses easier to see when handling.
- Principle of operation: When hydrated and placed on the cornea, the lenses act as a refracting medium to focus light rays on the retina.
- Energy source: N/A

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

Non-Clinical Testing:
Alcon has performed stability testing of the modified (subject) DAILIES TOTAL 1® contact lenses to verify their stability profile and to confirm that the stability behavior of these lenses matches the predicate device, i.e. currently commercialized DAILIES TOTAL 1® contact lenses. Results to-date demonstrate that all tested lens attributes remain within proposed acceptance limits at both ambient 25 °C/40% RH and the accelerated condition 45 °C/20% RH. Average and individual results for power (±0.25 D), base curve (±0.20 mm), and diameter (±0.20 mm) were consistently within specification across all lots and intervals. Visual inspection confirmed that all samples passed applicable stability inspection standards. The results support the conclusion that DAILIES TOTAL 1® dimensional stability trends are robust and predictable.

Clinical Testing:
A clinical trial has been successfully completed comparing test delefilcon A lenses (subject device) to the comparator or predicate device, commercially available DAILIES TOTAL 1® (DT1) delefilcon A contact lenses. This clinical investigation was a prospective, randomized, double-masked, crossover, multi-center clinical trial. The purpose of this study was to evaluate the lens fit characteristics and subjective assessments of comfort and vision of delefilcon A soft contact lenses in different base curves and diameters. Noninferiority was demonstrated for all primary and key exploratory effectiveness endpoints. Across analyses, both lenses showed stable, centered fit classifications and high subjective ratings. In conclusion, the clinical findings were consistent between lenses within the context of this study and did not identify additional safety concerns for the subject device under the evaluated daily-wear, single-use conditions.

Overall Conclusion:
The results of the nonclinical bench testing, including stability testing, demonstrated that the device stability characteristics of the subject DAILIES TOTAL1® soft contact lenses remain unchanged from those of the predicate lenses. Clinical evaluation of DAILIES TOTAL1® lenses with the proposed change has proven that these lenses perform noninferior to the predicate lenses, confirming that the proposed change can be made without impacting the established clinical safety and effectiveness / performance of the device. Alcon believes the testing and documentation provided herein sufficiently support the claim of substantial equivalence of the subject device with current DAILIES TOTAL1® contact lenses, as originally cleared under K113168, with most recent update under K243909.