November 16, 2023

Alcon Laboratories, Inc.
Martina Heim
Director, Global Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K232921
Trade/Device Name: DAILIES TOTAL1®; DAILIES TOTAL1® Toric; 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: September 19, 2023
Received: September 19, 2023

Dear Martina Heim:

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232921

Device Name

DAILIES TOTAL1®;
DAILIES TOTAL1® Toric;
DAILIES TOTAL1® Multifocal;
DAILIES TOTAL1® Multifocal Toric

Indications for Use *(Describe)*

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® Toric (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 (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® 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.

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.

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: 2023-11-08

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	(678) 415-3565
Applicant Contact	Dr. Martina Heim
Applicant Contact Email	martina.heim@alcon.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	DAILIES TOTAL1®; DAILIES TOTAL1® Toric; DAILIES TOTAL1® Multifocal; DAILIES TOTAL1® Multifocal Toric
Common Name	Soft (hydrophilic) contact lens
Classification Name	Lenses, Soft Contact, Daily Wear
Regulation Number	886.5925
Product Code	LPL

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K113168	DAILIES TOTAL1; DALIES TOTAL1 FOR ASTIGMATISM; DAILI	LPL

Device Description Summary

21 CFR 807.92(a)(4)

DAILIES TOTAL1® (delefilcon A) soft contact lenses may be made available in sphere, toric, multifocal, and multifocal toric lens designs. The lens material, delefilcon A, is a silicone hydrogel with a water content of approximately 33% and a water gradient surface treatment. It is considered a Group 5C material according to ISO 18369-1:2017. 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® Toric (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 (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® 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.

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.

Technological Comparison 21 CFR 807.92(a)(6)

The predicate and subject DAILIES TOTAL1® (delefilcon A) soft contact lenses have the same lens material properties:
- Refractive Index (hydrated): 1.42
- Light Transmittance: ≥ 93% (@ 610 nm, -1.00 D)
- Oxygen Permeability: 140 barrer
- Water Content: 33% by weight in normal saline

The modified lenses are tinted using Reactive Blue 247.

The lenses are cast-molded and have a water gradient surface treatment. Lenses may be made available in the following parameter range:
- Diameter: 13.0 to 15.0 mm
- Base Curve: 8.0 to 9.2 mm
- Power Range: +20.0 D to -20.0 D
- Center Thickness: 0.070 mm to 0.340 mm (varies with power)
- Cylinder Power: Up to 5.00 D
- Cylinder Axis: 1° to 180°
- ADD power: Up to 5.00 D

Moist heat sterilization is used to terminally sterilize the lenses. Lenses are supplied sterile in sealed blister packs containing isotonic phosphate buffered saline solution with polymeric wetting agents that form the water gradient surface.

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

Performance testing for the modified DAILIES TOTAL1® (delefilcon A) soft contact lenses followed the May 1994 FDA guideline titled Premarket Notification 510(k) Guidance Document for Class II Contact Lenses. Nonclinical bench testing was conducted using GxP conditions, and, where applicable ISO 18369-2, -3, -4 standards. Lens material properties, dimensional and optical properties, and extractables and residuals were demonstrated to be substantially equivalent to the predicate device. Results of an ongoing shelf-life stability study demonstrate that packaged lenses remain sterile and stable for the labeled expiration date.

Nonclinical biocompatibility testing was conducted in accordance with the GLP regulation (21 CFR Part 58) and relevant parts of the ISO 10993 series. Specifically, the following testing was completed, all with passing results:
- Cytotoxicity Studies (lens, lens extracts, and package saline) per ISO 10993-5
- Ocular Irritation / Toxicity (Ocular) in Rabbits
  - Ocular biocompatibility of soft contact lenses, 22-day Evaluation per ISO 9394
  - Ocular biocompatibility of package saline, 22-Day Evaluation per ISO 9394
  - Primary ocular irritation studies per ISO 19993-10 (lens extracts and package saline)
- Sensitization Studies (lens extracts and package saline) per ISO 10993-10
- Acute Systemic Toxicity Study in Mice (lens extracts) per ISO 10993-11
- Genotoxicity Studies (lens extracts and package saline) per ISO 10993-12

Additional biocompatibility testing was conducted to support minor changes of the primary packaging foil lidding material. Biocompatibility testing for the blister shells was previously submitted for the predicate device.
- Cytotoxicity Studies (foil lidding, foil lidding extracts) per ISO 10993-5
- Ocular Irritation / Toxicity (Ocular) in Rabbits
  - Primary ocular irritation studies per ISO 19993-10 (foil lidding extracts)

• Acute Systemic Toxicity Study in Mice (foil lidding extracts) per ISO 10993-11

The scope of the device modification did not require clinical testing to establish safety and effectiveness of the subject device. The claim of substantial equivalence to a lens with an existing USAN and the same manufacturing process is supported by nonclinical testing.

Non-clinical data demonstrates that the subject device is as safe, as effective, and performs as well as or better than the legally marketed, predicate device. Modified DAILIES TOTAL1® (delefilcon A) soft contact lenses are substantially equivalent to the predicate device lenses, and similar to other daily wear soft contact lenses in terms of technological characteristics and intended use.