January 18, 2019

Alcon Laboratories, Inc.
Martina Heim
Global Project Regulatory Director, Global Regulatory Affairs, Vision Care
6201 South Freeway
Fort Worth, TX 76134

Re: K182782
Trade/Device Name: DAILIES TOTAL1 Soft Contact Lenses: DAILIES TOTAL1, DAILIES TOTAL1 Asphere, 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 17, 2018
Received: December 21, 2018

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 (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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

J Angelo Green -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K182782

Device Name
DAILIES TOTAL1 soft contact lenses:
DAILIES TOTAL1, DAILIES TOTAL1 Asphere, DAILIES TOTAL1 for ASTIGMATISM, DAILIES TOTAL1 Multifocal, DAILIES TOTAL1 Multifocal Toric

Indications for Use *(Describe)*

DAILIES TOTAL1 (delefilcon A) and DAILIES TOTAL1 Asphere (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 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 (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, 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

This 510(k) summary document has been prepared in accordance with section 21 CFR 807.92.

## I. Submitter of the 510(k)


| | |
|---|---|
| Company: | Alcon Laboratories, Inc.<br>6201 South Freeway<br>Fort Worth, TX 76134-2099, USA |
| Primary Contact Person: | Martina Heim, Ph.D., RAC |
| Phone: | (678) 415-3565 |
| Fax: | n/a |
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| Back up Contact Person: | Sherri Lakota |
| Phone: | (817) 615-5472 |
| Fax: | 817-302-4574 |
| Email: | Sherri.Lakota@alcon.com |
| Date Prepared: | 17 December 2018 |


## II. Devices Subject to this 510(k)

| | |
|---|---|
| Trade Names: | *DAILIES TOTAL1® soft contact lenses:*<br>DAILIES TOTAL1®, DAILIES TOTAL1® Asphere, DAILIES TOTAL1® for ASTIGMATISM, DAILIES TOTAL1® Multifocal, DAILIES TOTAL1® Multifocal Toric<br>*Alternate family trade name*: DAILIES TOTAL1® PRO |
| Common Name: | Soft contact lens |
| Classification Name: | Soft (hydrophilic) contact lens [for daily wear] |
| Device Classification: | 21 CFR 886.5925 (b) (1) |
| Product Code: | LPL, MVN |

## III. Predicate Device

The subject device is a modification of the currently commercialized DAILIES TOTAL1® (delefilcon A) soft contact lens. The predicate DAILIES TOTAL1 soft contact lenses have received FDA clearance per Premarket Notification 510(k) K113168, with recent updates cleared under K180398 and K180669.

## IV. Device Description

The DAILIES TOTAL1® family of daily disposable soft contact lenses are made from delefilcon A, a silicone hydrogel with a water content of approximately 33% and a water gradient surface treatment. The delefilcon A silicone hydrogel material is considered a Group 5C material according to ISO 18369-1:2017 (defined as: "enhanced oxygen permeable material", water content less than 50%, no ionic monomer or oligomer at pH 6 to pH 8).

Modified DAILIES TOTAL1® lenses contain a combination of light absorbing chromophores. Specifically, benzotriazole UV absorbing monomers are used to block UV radiation and, additionally, reduce transmittance in the range from 380 nm to 450 nm. The color additive [phthalocyaninato (2-)] copper (synonym: copper phthalocyanine) provides a light blue-green handling tint.

Lens designs for the modified DAILIES TOTAL1® (delefilcon A) lenses include spherical, asphere, toric, multifocal, and multifocal toric lenses in the following parameter range:

- Diameter Range: 13.0 to 15.0 mm
- Base Curve Range: 8.0 to 9.2 mm
- Power Range: -20.00D to +20.00D
- Center Thickness: varies with design and power (0.09 mm for -3.00D spherical)

Lenses have the following properties:

- Refractive index: 1.42 (hydrated)
- Water content: 33% by weight in normal saline
- Oxygen permeability 140 barrer units measured at 35 °C (intrinsic Dk - Coulometric method)

- % Light transmittance, visible: 90 ± 5% (average over 380 to 780 nm)
- % UV transmittance UVA (315-380 nm): < 10.0%
  UVB (280-315 nm): < 1.0%

Lenses are supplied sterile in sealed blister packs containing isotonic phosphate buffered saline solution (PBS) with polymeric wetting agents that form the water gradient surface. The compatibility and package integrity of the blister pack packaging system has been demonstrated and successfully used for other marketed lens products, and packaged lenses are effectively steam sterilized in a validated autoclave. Blister pack containers are labeled with the lens parameters, lot number and product expiration date. The expiration date has been established through stability studies that have assessed the chemical stability of the lens and package integrity (ability to maintain sterility). Shelf-life studies are ongoing to further extend the labeled expiration date.

## V. Indications for Use

DAILIES TOTAL1 (delefilcon A) and DAILIES TOTAL1 Asphere (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 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 (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, 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.

## VI. Comparison to Technological Characteristics with the Predicate Device

Table 5-1 summarizes the characteristics of the modified device compared to the predict devices:

Table 5-1 Substantial Equivalence Comparison

| | Predicate Device | Subject Device |
|---|---|---|
| **Trade Name (brand)** | DAILIES TOTAL1® | DAILIES TOTAL1® |
| **Submission Number** | K113168 | *510(k) # to be assigned* |
| **Device Classification Name** | Daily Wear Soft Contact Lens 21 CFR 886.5925 (b)(1) | Daily Wear Soft Contact Lens 21 CFR 886.5925 (b)(1) |
| **Intended Use** | Vision correction | Same |
| **Wearing Schedule** | Daily wear | Same |
| **Replacement Schedule** | Daily disposable | Same |
| **Material Classification** | Group 5C, low water silicone hydrogel according to ISO 18369-1:2017 | Same |
| **Lens Material** | Delefilcon A | Same |
| **Surface Treatment** | Water gradient surface treatment | Same |
| **Manufacturing Method** | LightStream (molded) | Same |
| **Visibility Tint** | [phthalocyaninato (2-)] copper | Same |
| **Lens marks** | none | Molded lens marks (e.g. fiducial mark for toric lenses) |
| **Lens Designs** | Spherical, toric, multifocal, multifocal toric | Spherical, asphere, toric, multifocal, multifocal toric |

| | Predicate Device | Subject Device |
|---|---|---|
| **Power Range** | +20.00 to -20.00D | Same |
| **Base Curve Range** | 8.0 to 9.2 mm | Same |
| **Diameter Range** | 13.0 to 15.0 mm | Same |
| **Water Content** | 33% | Same |
| **Refractive Index** | 1.42 | Same |
| **Oxygen Permeability** | 140 barrer units* | Same |
| **Sterilization** | Steam sterilization, validated autoclave | Same |
| **Packaging** | Polypropylene blister shell sealed with polyester coated aluminum foil lidding | Same |
| **Package Storage Saline Solution** | Phosphate buffered saline (PBS) with polymeric wetting agents | Same |

* 1 barrer = x $10^{-11}$ ($cm^2$/sec)(ml $O_2$ /ml x mm Hg)

## VII. Performance Data

Performance testing was performed in accordance with the May 1994 FDA guideline, *Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses,* and applicable ISO standards for contact lenses. Performance data are provided in support of the substantial equivalence determination.

### Non-clinical Testing

A series of non-clinical testing was performed to characterize the lens material properties of the modified DAILIES TOTAL1® lenses and demonstrate the substantial equivalence of the modified device to the predicate device. Light transmittance properties (incl. UV and UV-Vis) are supported by testing in accordance with ISO 18369-3:2017. Non-clinical biocompatibility testing was conducted in accordance with the GLP regulation (21 CFR Part 58). All biocompatibility testing was conducted in accordance with the GLP regulation (21 CFR Part 58) and relevant ISO 10993 series biocompatibility standards.

The results of all non-clinical testing demonstrate:

- Physicochemical characteristics of the modified device are substantially equivalent to the predicate lens, currently commercialized DAILIES TOTAL1® lenses.
- The lens material, lens extracts and package saline of the device are non-toxic, non-irritating, non-sensitizing, and non-genotoxic.
- Successful stability testing supports the labeled expiration date.

### Clinical Testing

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

## VIII. Conclusions

DAILIES TOTAL1® (delefilcon A) soft contact lenses as modified are substantially equivalent to the predicate device lenses, DAILIES TOTAL1, and similar to other daily wear soft contact lenses in terms of technological characteristics and intended use.

Non-clinical data demonstrates that the modified device is as safe, as effective, and performs as well as or better than the legally marketed, predicate device, unmodified DAILIES TOTAL1 soft contact lenses.