February 4, 2022

CooperVision, Inc.
Marie Dutton
Regulatory Affairs Manager
6101 Bollinger Canyon Road, Suite 500
San Ramon, CA 94583

Re: K220070
Trade/Device Name: MyDay (stenfilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens, Avaira Vitality (fanfilcon A) Soft (Hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: January 6, 2022
Received: January 10, 2022

Dear Marie Dutton:

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/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 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 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, 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.

510(k) Number *(if known)*
K220070

Device Name
MyDay (stenfilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens

Indications for Use *(Describe)*

MyDay (stenfilcon A) ASPHERE Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

MyDay (stenfilcon A) TORIC Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

MyDay (stenfilcon A) MULTIFOCAL Soft Contact lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

MyDay (stenfilcon A) MULTIFOCAL TORIC Soft Contact lenses are indicated for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have -10.00 diopters of astigmatism or less.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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.

510(k) Number *(if known)*
K220070

Device Name
Avaira Vitality (fanfilcon A) Soft (Hydrophylic) Contact Lens

Indications for Use *(Describe)*
AVAIRA VITALITY SPHERE and ASPHERE (fanfilcon A) Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.
AVAIRA VITALITY (fanfilcon A) TORIC Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.
AVAIRA VITALITY (fanfilcon A) MULTIFOCAL Soft lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with add powers from +0.25 to +4.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.
AVAIRA VITALITY (fanfilcon A) MULTIFOCAL TORIC Soft Contact lenses are indicated for the optic correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes in powers of -20.00 to +20.00 diopters with add powers from +0.25 to +4.00 diopters and astigmatism corrections from -0.25 to -10.00 diopters.

Eye Care Practitioners may prescribe the Avaira Vitality (fanfilcon A) Soft Contact lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement or for single-use disposable wear.
When prescribed for frequent/planned replacement, the Avaira Vitality (fanfilcon A) Soft Contact lens is to be cleaned, rinsed and disinfected each time the lens is removed. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection only.
When prescribed for single-use disposable wear, the Avaira Vitality (fanfilcon A) Soft Contact lens is to be discarded after each removal.

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.

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K220070
510(k) Summary

I. SUBMITTER:

CooperVision, Inc.
6101 Bollinger Canyon Road, Suite 500
San Ramon, CA 94583

Contact Person:
Marie Dutton
Regulatory Affairs Manager
CooperVision, Inc.
6101 Bollinger Canyon Road, Suite 500
San Ramon, CA 94583
Phone: (925) 660-4474
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Date Prepared:
February 3, 2022

II. DEVICE:

A. MyDay (stenfilcon A)

Trade Name:	MyDay (stenfilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens
Common Name:	Soft (hydrophilic) Contact Lens
Classification Name:	Lens, Contact, (Disposable) [21 CFR 886.5925 (b)(1)]
Regulatory Class:	II
Product Code:	LPL, MVN
Classification Panel:	Ophthalmic

B. Avaira Vitality (fanfilcon A)

Trade Name:	Avaira Vitality (fanfilcon A) Soft (Hydrophylic) Contact Lens
Common Name:	Soft (hydrophilic) Contact Lens
Classification Name:	Lens, Contact, (Disposable) [21 CFR 886.5925 (b)(1)]
Regulatory Class:	II
Product Code:	LPL, MVN
Classification Panel:	Ophthalmic

III. PREDICATE DEVICE:

A. MyDay (stenfilcon A)

The predicate device for MyDay (stenfilcon A) is CooperVision's MyDay (stenfilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens cleared under 510(k) K190965.

B. Avaira Vitality (fanfilcon A)

The predicate device for Avaira Vitality (fanfilcon A) is CooperVision's Avaira Vitality (fanfilcon A) Soft (Hydrophilic) Contact Lens cleared under 510(k) K213164.

IV. DEVICE DESCRIPTION:

A. MyDay (stenfilcon A)

MyDay Contact Lenses are available as Asphere, Toric, Multifocal, and Multifocal Toric lens designs.

The MyDay material, stenfilcon A, is primarily a random copolymer of polydimethylsiloxane methacrylate and vinylmethyl acetamide. The lenses have a blue tint which is added to make the lens more visible for handling. The lenses also contain a UV absorbing monomer, benzotriazolyl methacrylate, which is used to block UV radiation.

When placed on the cornea in its hydrated state, the MyDay Soft (Hydrophilic) Contact Lens acts as a refracting medium to focus light rays on the retina.

MyDay (stenfilcon A) contact lens parameters are:

- Chord Diameter: 13.0 mm to 15.5 mm
- Base Curve: 8.4 ± 0.5 mm and 8.7 ± 0.5 mm
- Center Thickness: 0.08 mm to 0.218 mm (varies with power)
- Powers: -20.00D to +20.00D
- Cylinder Powers: -0.25D to -10.00D
- Axis: 0° to 180° in 10° increments
- Add Power Range: +0.50 to +4.00

The physical/optical properties of the lens are:

- Specific Gravity: 1.033
- Refractive Index: 1.401
- Light Transmittance: 96%
- Surface Character: Hydrophilic
- Water Content: 54%
- Oxygen Permeability: 80×10^{-11} [$(cm^2/sec) \times (ml\ O_2)/(ml \times mm\ Hg)$]

B. Avaira Vitality (fanfilcon A)

Avaira Vitality Contact Lenses are available as Sphere, Asphere, Toric, Multifocal, and Multifocal Toric lens designs.

The Avaira Vitality material, fanfilcon A, is primarily a random copolymer of polydimethylsiloxane methacrylate and vinylmethyl acetamide. The lenses have a blue tint which is added to make the lens more visible for handling.

The lenses also contain a UV absorbing monomer, benzotriazolyl methacrylate, which is used to block UV radiation.

When placed on the cornea in its hydrated state, the Avaira Vitality Soft (Hydrophilic) Contact Lens acts as a refracting medium to focus light rays on the retina.

Avaira Vitality (fanfilcon A) contact lens parameters are:

- Diameter: 13.5 mm to 15.5 mm
- Base Curve: 8.2 mm and 9.2 mm
- Center Thickness: 0.06 mm to 0.6 mm (varies with power)
- Powers: -20.00 D to +20.00 D
- Cylinder Powers (Toric and Multifocal Toric): -0.25 D to -10.00 D
- Axis (Toric and Multifocal Toric): 0° to 180°
- Add Power Range (Multifocal and Multifocal Toric): +0.25 D to +4.00 D

The physical/optical properties of the lens for the subject device and the predicate device are identical.

The physical/optical properties of the lens are:

- Specific Gravity: 1.026
- Refractive Index: 1.398 ± 0.005
- Light Transmittance: 98% +2/-5%
- Surface Character: Hydrophilic
- Water Content: 55% ± 2%
- Oxygen Permeability: $90x10^{-11}$ [$(cm^2/sec)x(ml\ O_2)/(ml\ x\ mm\ Hg)$]

V. INDICATIONS FOR USE:

A. MyDay (stenfilcon A)

MyDay (stenfilcon A) ASPHERE Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

MyDay (stenfilcon A) TORIC Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

MyDay (stenfilcon A) MULTIFOCAL Soft Contact lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.

MyDay (stenfilcon A) MULTIFOCAL TORIC Soft Contact lenses are indicated for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have -10.00 diopters of astigmatism or less.

B. Avaira Vitality (fanfilcon A)

AVAIRA VITALITY SPHERE and ASPHERE (fanfilcon A) Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

AVAIRA VITALITY (fanfilcon A) TORIC Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

AVAIRA VITALITY (fanfilcon A) MULTIFOCAL Soft lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with add powers from +0.25 to +4.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

AVAIRA VITALITY (fanfilcon A) MULTIFOCAL TORIC Soft Contact lenses are indicated for the optic correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes in powers of -20.00 to +20.00 diopters with add powers from +0.25 to +4.00 diopters and astigmatism corrections from -0.25 to -10.00 diopters.

Eye Care Practitioners may prescribe the Avaira Vitality (fanfilcon A) Soft Contact lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement or for single-use disposable wear.

When prescribed for frequent/planned replacement, the Avaira Vitality (fanfilcon A) Soft Contact lens is to be cleaned, rinsed and disinfected each time the lens is removed. The contact lens is to be discarded after the

recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection only.

When prescribed for single-use disposable wear, the Avaira Vitality (fanfilcon A) Soft Contact lens is to be discarded after each removal.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The technological characteristics of the subject device and the predicate device are compared in the tables below.

A. MyDay (stenfilcon A)

Technology/Material Comparison		
	Predicate Device	**Subject Device**
Product Name	CooperVision MyDay (stenfilcon A)	Same
Material USAN Name	stenfilcon A	Same
FDA Category (Group)	Silicone Hydrogel	Same
Manufacturing Method	Molded	Same
Sterilization	Moist Heat	Same
Packaging Materials	Injection molded polypropylene blisters covered by aluminum foil laminate; blister strips are packed into printed cartons	Same
Packaging Solution	Phosphate Buffered Saline Solution with Tween	Same
Visibility Tint	RB246	Same
UV Blocker	Norbloc	Same

B. Avaira Vitality (fanfilcon A)

Technology/Material Comparison		
	Predicate Device	**Subject Device**
Product Name	CooperVision Avaira Vitality (fanfilcon A)	Same
Material USAN Name	fanfilcon A	Same
FDA Category (Group)	Silicone Hydrogel	Same
Manufacturing Method	Molded	Same
Sterilization	Moist Heat	Same
Primary Packaging Materials	Blister, Foil	Same
Packaging Solution	Phosphate buffered saline solution	Same
Visibility Tint	RB246	Same
UV Blocker	Norbloc	Same

VII. PERFORMANCE DATA

Results from non-clinical studies were provided in support of the substantial equivalence determination.

Performance testing:

In accordance with the Premarket Notification [510(k)] Guidance Document for Daily Wear Contact Lenses, May 12, 1994 amended June 28, 1994, the following battery of testing was performed. All tests were conducted in accordance with the GLP regulation (21 CFR Part 58) or according to valid scientific protocols. Each test was conducted according to the ANSI, ISO, and/or ASTM standard indicated:

- Contact angle per ANSI Z80.20-2016
- Water content per BS EN ISO 18369-2:2017 and BS EN ISO 18369-4:2017
- Mechanical properties per ANSI Z80.20-2016 and ASTM D1708-02a
- Total extractables per ANSI Z80.20-2016 and BS EN ISO 18369-4:2017
- Dimensional/optical parameters per BS EN ISO 18369-2:2017 and BS EN ISO 18369-3:2017

Biocompatibility testing:

No biocompatibility testing was required as there are no changes to the lens formulation or manufacturing process.

Equivalency was demonstrated from an ISO 10993-18:2020 chemical profiling perspective between the modified and unmodified stenfilcon A contact lenses.

VIII. CONCLUSIONS:

This 510(k) is submitted in accordance with the May 12, 1994 Premarket Notification [510(k)] Guidance Document for Daily Wear Contact Lenses, amended June 28, 1994, for a manufacturing process change and a change to the purity specification. Because the predicate device lens material characteristics, primary packaging materials and packaging solution are identical to the subject device, non-clinical data presented are adequate to support substantial equivalence. Therefore, the subject MyDay (stenfilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens is considered substantially equivalent to its predicate device, and the subject Avaira Vitality (fanfilcon A) Soft (Hydrophilic) Contact Lens is considered substantially equivalent to its predicate device.