October 26, 2021

CooperVision, Inc.
Ahanitha Ashok
Regulatory Affairs Specialist
6101 Bollinger Canyon Road, Suite 500
San Ramon, CA 94583

Re: K213164
Trade/Device Name: 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: September 27, 2021
Received: September 28, 2021

Dear Ahanitha Ashok:

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)*

K213164

Device Name

Avaira Vitality (fanfilcon A) Soft (Hydrophilic) Contact Lens

Indications for Use *(Describe)*

Sphere/Asphere:

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.

Toric:

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.

Multifocal:

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.

Multifocal Toric:

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 from -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 fo 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.**

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

K213164

**510(k) Summary**

## I. SUBMITTER:

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

**Contact Person:**
Ahanitha Ashok
Regulatory Affairs Specialist
6101 Bollinger Canyon Road, Suite 500
San Ramon, CA 94583
Phone: (925) 660-4482
E-mail: aashok@coopervision.com

**Date Prepared:**
October 22, 2021

## II. DEVICE:

| | |
|---|---|
| Trade Name: | Avaira Vitality (fanfilcon A) Soft (Hydrophilic) Contact Lens |
| Common Name: | Soft (Hydrophilic) Contact Lens |
| Classification Name: | Lens, Soft Contact, (Daily Wear) [21 CFR 886.5925 (b)(1)] |
| Regulatory Class: | II |
| Product Code: | LPL, MVN |
| Classification Panel: | Ophthalmic |

## III. PREDICATE DEVICE:

- CooperVision's Avaira Vitality (fanfilcon A) Soft (Hydrophilic) Contact Lens, K160803

## IV. DEVICE DESCRIPTION:

The Avaira Vitality (fanfilcon A) Contact Lens visibility tinted with UV blocker is available as sphere/asphere lens, toric lens, multifocal lens, and multifocal toric lens.

The lenses are made of a silicone hydrogel material which is not surface treated and is characterized by high oxygen permeability (Dk). The Avaira Vitality (fanfilcon A) Contact Lens is tinted blue using Reactive Blue #246 to make the lens more visible for handling. A Norbloc UV blocker is used to reduce the amount of ultraviolet light transmitted into the eye. The Avaira Vitality (fanfilcon A) lens is supplied sterile, packaged in a phosphate buffered saline solution. The composition of the lens is 45% fanfilcon A and 55% water by weight when
hydrated and stored in buffered saline solution.

In its hydrated state, the Avaira Vitality (fanfilcon A) Contact Lens visibility tinted, with UV blocker, when placed on the cornea, acts as a refracting medium to focus light rays on the retina.

The lens has a hemispherical flexible shell, which covers the cornea and a portion of the adjacent sclera, with the following dimensions:

- Diameter: 13.5 mm to 15.0 mm
- Base Curve: 8.2 mm to 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): -0.25 D to -10.00 D
- Axis (Toric): 0˚ to 180˚
- Add Power Range (Multifocal) +0.25 D to +4.00 D

The physical/optical properties of the lenses 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: $90 \times 10^{-11}$ [($cm^2$/sec) x (ml $O_2$)/ (ml x mm Hg)]

## V. INDICATIONS FOR USE:

| Lens Design | Indication |
|---|---|
| Sphere | 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. |
| Toric | 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. |
| Multifocal | 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. |
| Multifocal Toric | 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 table below.

| Technology/Material Comparison | | |
|---|---|---|
| | **Predicate Device** | **Subject Device** |
| Product Name | Avaira Vitality (fanfilcon A) Soft (Hydrophilic) Contact Lens | Same |
| Material USAN Name | fanfilcon A | Same |
| 510(k) number | K160803 | K213164 |
| FDA Category (Group) | Silicone Hydrogel | Same |
| Manufacturing Method | Molded | Same |
| Sterilization | Moist Heat | Same |
| Primary Packaging | Blister, Foil | Same |
| Packaging Solution | Phosphate buffered saline solution | Same |
| Visibility Tint | Reactive Blue # 246 | Same |

## VII PERFORMANCE DATA:

The performance specifications/parameters of the subject device and the predicate device are compared in the table below.

| Performance Specifications/Parameters Comparison | | |
|---|---|---|
| | **Predicate Device Avaira Vitality (fanfilcon A) K160803** | **Subject Device Avaira Vitality (fanfilcon A) K213164** |
| Water Content % | 55% | Same |
| Refractive Index@$20^0$ C | 1.40 | Same |
| Specific Gravity g/mL | 1.026 | Same |
| Oxygen Permeability (Dk)* | 90 | Same |
| Base Curve, mm | 8.4 | Same |
| Diameter, mm | 14.2 | Same |

*Dk units: x $10^{-11}$ ($cm^2$/sec) x (ml $O_2$)/ml x mmHg)

## VIII. BIOCOMPATIBILITY TESTING:

In accordance with the GLP regulation (21 CFR Part 58), the following battery of biocompatibility testing was performed on the lens and the packaging solution in support of the substantial equivalence determination:

- ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

## IX. 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 lens extract non-polymeric residuals specification change. The modification does not warrant performance testing to support substantial equivalence. Because the predicate device lens material characteristics, primary packaging materials and packaging solution are identical to the subject device, limited biocompatibility testing is adequate to support substantial equivalence. Therefore, the subject device is considered substantially equivalent to the predicate device.