DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 13, 2016

CooperVision, Inc.
Mr. Dan O'Mara
Regulatory Affairs Manager
6150 Stoneridge Mall Rd., Suite 370
Pleasanton, CA 94588

Re: K160803
Trade/Device Name: Avaira Vitality (fanfilcon A) Soft (hydrophilic) Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: June 1, 2016
Received: June 2, 2016

Dear Mr. O'Mara:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Denise L. Hampton -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160803

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 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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510(k) Summary

Date: 6 July 2016

Submitter Information:

CooperVision, Inc.
6150 Stoneridge Mall Road
Suite 370
Pleasanton, CA 94588
USA
(800) 972-6724

Contact:

Dan O'Mara
Regulatory Affairs Manager
domara@coopervision.com
(585) 756-9589

Device Identification:

Common Name:	Soft Contact Lens
Trade Name:	AVAIRA VITALITY (fanfilcon A) Soft Contact Lens
Class. Name:	Soft (hydrophilic) Contact Lens – Daily Wear
Classification:	Class II [21 CFR 886.5925 (b) (1)]
Product Code:	LPL, MVN

Predicate Device(s):

Primary (Indication, Wear Schedule and Material)

CooperVision AVAIRA (enfilcon A)
K113759
(Silicone Hydrogel, Daily wear - *frequent replacement*)

Secondary (Indication, Wear schedule and Material)

CooperVision MyDay (stenfilcon A)
K131378
(Silicone Hydrogel, Daily wear - *single use*)

Description of Device

- The AVAIRA VITALITY (fanfilcon A) Contact Lens visibility tinted with UV blocker is available as a 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 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.

Indications for Use

Lens Design	Indication
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 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.

Technological Characteristics:

The technological characteristics of the AVAIRA VITALITY (fanfilcon A) Contact Lenses are compared to the characteristics of the predicate device, CooperVision AVAIRA (enfilcon A) Contact Lens, in the following tables.

Material Comparison		
	Predicate Device	**Subject Device**
Product Name	CooperVision AVAIRA	CooperVision AVAIRA VITALITY
Material USAN Name	enfilcon A	fanfilcon A
510(k) Number	K113759	TBD – Current Submission
FDA Category (Group)	Silicone Hydrogel	Silicone Hydrogel
Manufacturing Method	Molded	Molded
Sterilization	Moist Heat	Moist Heat
Packaging	Blister	Blister
Visibility Tint	Phthalocyanine Blue	Reactive Blue #246

Parameter Comparison		
	Predicate Device	**Subject Device**
	CooperVision AVAIRA (enfilcon A) K113759	CooperVision AVAIRA VITALITY (fanfilcon A) TBD – Current Submission
Water Content, %	46%	55%
Refractive Index @ 20°C	1.40	1.40
Specific Gravity g/mL	1.06	1.026
Oxygen Permeability (Dk)*	100	90
Base Curve, mm	8.5	8.4
Diameter, mm	14.2	14.2

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

Technological Characteristics:

The technological characteristics of the AVAIRA Vitality (fanfilcon A) Contact Lenses are compared to the characteristics of the predicate device, CooperVision MyDay (stenfilcon A) Contact Lens, in the following tables.

Material Comparison		
	Predicate Device	**Subject Device**
Product Name	CooperVision MyDay	CooperVision AVAIRA VITALITY
Material USAN Name	stenfilcon A	fanfilcon A
510(k) Number	K131378	TBD – Current Submission
FDA Category (Group)	Silicone Hydrogel	Silicone Hydrogel
Manufacturing Method	Molded	Molded
Sterilization	Moist Heat	Moist Heat
Packaging	Blister	Blister
Visibility Tint	Reactive Blue #246	Reactive Blue #246

Parameter Comparison		
	Predicate Device	**Subject Device**
	CooperVision MyDay (stenfilcon A) K131378	CooperVision AVAIRA VITALITY (fanfilcon A) TBD – Current Submission
Water Content, %	54%	55%
Refractive Index @ 20oC	1.40	1.40
Specific Gravity g/mL	1.033	1.026
Oxygen Permeability (Dk)*	80	90
Base Curve, mm	8.4	8.4
Diameter, mm	14.2	14.2

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

Non-clinical Testing

A series of in-vitro and in-vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the contact lens. All tests were conducted in accordance with the GLP regulation (21 CFR Part 56) or according to valid scientific protocols.

The results of the non-clinical testing/evaluation demonstrate that:

- The lens material and/or extracts are non-toxic, non-irritating and non-sensitizing under the experimental conditions; and
- The lens physical and material properties are consistent with currently marketed lenses.

Clinical Testing

A three-month clinical study was completed to evaluate the safety and efficacy of the AVAIRA VITALITY (fanfilcon A) Contact Lens for daily wear with a replacement schedule of one month (up to 30 days).

The study was a multi-center, randomized, masked, concurrent control study that evaluated ninety (90) male and female subjects who were dispensed lenses in a 2:1 ratio with 60 subjects dispensed into the Test lenses and 30 subjects dispensed into the Control lenses. The primary outcome measures were slit lamp (biomicroscopy) findings and adverse event rates along with lens visual acuity comparisons between the Test and the Control contact lenses. Secondary outcome measures included average lens wearing times and subjective lens comfort assessed by frequency or symptoms.

The Test contact lens was found to be substantially equivalent to the Control contact lens for safety and efficacy.

Conclusion Drawn from Studies

Validity of Scientific Data:

A contract laboratory under Good Laboratory Practice Regulations conducted toxicology studies. Microbiology, chemistry, shelf-life stability, and leachability studies were conducted by CooperVision laboratories and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7.

Substantial Equivalence:

Information presented in this Premarket Notification establishes that the AVAIRA VITALITY (fanfilcon A) Contact Lens is as safe and effective as the predicate device when used in accordance with the labeled directions for use and the requested indication.

Risk and Benefits:

The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear basis. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.