DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 4, 2017

Supervision Optimax Sdn Bhd
Ms. Yap Peak Geeh
Regulatory Affairs Manager
Lot 38, Putra Industrial Park, Bukit Rahman Putra
40160 Sungai Buloh
Selangor Darul Ehsan, Malaysia

Re: K162223
Trade/Device Name: Aveo (omafilcon A) 1-Day Aspheric Soft (Hydrophilic) Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: November 25, 2016
Received: November 28, 2016

Dear Ms. Geeh:

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), 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

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)*
K162223

Device Name
Aveo (omafilcon A) 1-Day Aspheric Soft (Hydrophilic) Contact Lenses

Indications for Use *(Describe)*
Aveo (omafilcon A) 1-Day Aspheric Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in not aphakic persons with non-diseased eyes that are myopic or hyperopic and exhibit astigmatism of 1.00D or less that does not interfere with visual acuity. The contact lenses are intended for daily wear, single use and are to be discarded at the end of the day.

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

Preparation Date: 4th January 2017

1.0 Submitter:

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Contact Person : Yap Peak Geeh
Email Address : pg.yap@supervision.com.my

2.0 Device Identification:

Proprietary Name : Aveo (omafilcon A) 1-DAY Aspheric Soft (Hydrophilic) Contact Lens
Common Name : Soft (Hydrophilic) Contact Lens
Classification Name: Soft (Hydrophilic) Contact Lens
(21 CFR 886.5925, Product Code LPL)
Classification : Class II

3.0 Identification Of The Legally Marketed Devices that equivalency is claimed:

	Predicate Device	
Manufacturer	CooperVision, Inc	CooperVision, Inc
Device Name	Proclear (omafilcon A) Soft Contact Lenses	Proclear XC (omafilcon A) and Proclear 1 day (omafilcon A) Hydrophilic Contact Lenses for Daily Wear
510(k) Number	K112302	K061948
Regulation Number	21 CFR 886.5925	21CFR 886.5925
Regulatory Name	Soft (hydrophilic) contact lens	Soft (hydrophilic) contact lens
Regulatory Class	II	II
Product Code	LPL and MVN	LPL and MVN

4.0 Description of the Device:

The Aveo (omafilcon A) 1-DaY Aspheric Soft (Hydrophilic) Contact Lenses are single use daily disposable soft contact lens produced from the HEMA-MPC copolymer material. MPC is similar to phospholipids (e.g., phosphatidylcholine)

where molecules are found naturally in human cell membranes that improves the lens biocompatibility.

The contact lenses contain 58% water by weight and is sold in the blister package immersed in phosphate buffered packaging saline. RB 246 pigment conforms to 21 CFR Part 73.3106 is used to provide the handling blue tint for the lens.

The device is a corneal contact lens having a total diameter more than the visible iris diameter and is designed to be worn in its entirety on the cornea. The device has an aspheric front curve (external curve) which is tri-curve and spherical base curve (internal curve).

The contact lenses are hydrophilic, soft and it is supplied in sterile state.

5.0 Intended Use of the Device:

Aveo (omafilcon A)1-Day Aspheric Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in not aphakic persons with non-diseased eyes that are myopic or hyperopic and exhibit astigmatism of 1.00D or less that does not interfere with visual acuity. The contact lenses are intended for daily wear, single use and are to be discarded at the end of the day.

6.0 Summary of the Technological Characteristics of the Device:

Below is the summary of the technological characteristics of the Aveo (omafilcon A) 1-Day Aspheric Soft (Hydrophilic) Contact Lenses as compared to the predicate device.

Technological Characteristics			
Characteristic	**Subject Device**	**Predicate Device**	**Predicate Device**
Product Name	Aveo (omafilcon A)1-Day Aspheric Soft (Hydrophilic) Contact Lenses	Proclear Asphere	Proclear 1 day
Manufacturer	Supervision Optimax Sdn Bhd	CooperVision, Inc.	CooperVision, Inc.
510(K) Number	This submission	K112302	K061948
Intended Use	Aveo (omafilcon A)1-Day Aspheric Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in not aphakic persons with non-diseased eyes that are myopic or	Proclear Asphere (omafilcon A) Soft Contact lenses are indicated for daily wear for the correction of visual acuity in non-aphakic persons with non-diseased eyes that	Sphere and aspheric (omafilcon A) Soft (hydrophilic) contact lenses are indicated for daily wear for the correction of visual acuity in not aphakic persons with non-

	hyperopic and exhibit astigmatism of 1.00D or less that does not interfere with visual acuity. The contact lenses are intended for daily wear, single use and are to be discarded at the end of the day.	are myopic or hyperopic and exhibit astigmatism of 2.00D or less that does not interfere with visual acuity.	diseased eyes that are myopic or hyperopic and exhibit astigmatism of 2.00D or less that does not interfere with visual acuity.
Modality	Daily Wear	Daily Wear	Daily Wear
Lens Design	Aspherical	Aspherical	Aspheric
Material USAN Name	omafilcon A	omafilcon A	omafilcon A
FDA Category (Group)	Group II Non-ionic, High water	Group II Non-ionic, High water	Group II Non-ionic, High water
Manufacturing Method	Cast Molded	Finished Inside Polymerization System II	Cast Molded
Curing	Thermal Cure	Thermal Cure	Thermal Cure
Sterilization	Moist Heat (Steam) in Validated Autoclave	Moist Heat (Steam) in Validated Autoclave	Steam: Validated Autoclave
Packaging	Blister Pack	Blister Pack	Blister Pack
Visibility Tint	Reactive Blue Dye 246	VAT Blue 6	Vat Blue 6
Water Content	59% ± 2%	59% ± 2%	60% ± 2%
Package Saline	Phosphate Buffered Saline	Phosphate Buffers PEG200 and Tween 80	Not Stated
Refractive Index	1.4002	1.395 ± 0.005	1.40
Oxygen Permeability (Dk) x 10^{-11}	25.68	21.05	21
Light Transmission	98%	>90%	>90%
Base Curve	8.4mm to 8.8mm	8.0mm to 9.3mm	8.00mm to 9.50mm
Diameter $Ø_T$	14.0mm to 14.4mm	13.6mm to 15.2mm	13.0mm to 15.5mm
Power	-10.00 to +6.00	-20.00 to +20.00	-20.00 to +20.00

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

Physiochemical Studies

The physiochemical studies were conducted according to ISO 18369-4:2006 Ophthalmic Optics-Contact Lenses-Part 4: Physiochemical properties of contact lens materials and ISO 18369-3:2006 Ophthalmic Optic-Contact Lenses-Part 3: Measurement methods. The physical, optical and chemical properties of the lens are within established specifications for the lenses.

Toxicology Studies
Toxicology (in-vivo and in-vitro) studies reports show that the lenses are non-toxic and biocompatible with the ocular environment.

Test	Performance of Subject Device	Result
Cytotoxicity Test ISO 10993-5: 2009(E): Biological Evaluation of Medical Devices-Part 5: Tests for in vitro Cytotoxicity.	Non-cytotoxic.	Pass
Ocular Irritation Study in New Zealand White Rabbit ISO 10993-10: 2010(E): Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization.	Non-irritant to eyes of rabbits.	Pass
Skin Sensitization Study in Guinea Pigs ISO 10993-10: 2010(E): Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization.	Non-sensitizer	Pass
Acute Systemic Toxicity Study in Swiss Albino Mice ISO 10993-11: 2006(E): Biological Evaluation of Medical Devices-Part 11: Tests for in Systemic Toxicity.	Animals treated with the extract of the subject device did not show any systemic toxicity.	Pass

8.0 Clinical Test

The technological characteristics, formulation, manufacturing and sterilization processes are the same as the predicate device, Proclear Asphere (K112302) and Proclear 1 day (K061948). Therefore, no clinical studies were required to demonstrate the safety or effectiveness of the subject device.

9.0 Conclusion

The Aveo (omafilcon A) 1-Day Aspheric Soft (Hydrophilic) Contact Lenses are substantially equivalent to the predicate device, Proclear Asphere (K112302) and Proclear 1 day (K061948) in term of optical property, Physiochemical and pre-clinical toxicology. They are produced from the same material (omafilcon A), have the same functional and scientific technology, lens characteristics and the intended use is identical. It is concluded that the lenses are as safe, as effective and perform as well as the predicate devices.