June 8, 2018

Supervision Optimax SDN BHD
Yap Peak Geeh
Regulatory Affairs Manager
Lot 38, Putra Industrial Park, Bukit Rahman Putra
40160 Sungai Buloh, Selangor Dural Ehsan, Malaysia

Re: K180985
Trade/Device Name: Aveo (omafilcon 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: March 30, 2018
Received: April 13, 2018

Dear Yap Peak 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.

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,

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)*
K180985

Device Name
Aveo (omafilcon A) Soft (Hydrophilic) Contact Lenses

Indications for Use *(Describe)*

Aveo (omafilcon A) 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.

Aveo (omafilcon A) Toric Soft (Hydrophilic) Contact Lenses are indicated the 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 between 0.50D and 2.50D or less that does not interfere with visual acuity.

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

Frequent Planned Replacement Wear
When prescribed for frequent planned replacement wear the lenses are to be cleaned, rinsed and disinfected each time they are removed from the patients' eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lenses may be disinfected using a chemical disinfection system.

Disposable Wear
When prescribed for Daily Disposable Wear the 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(K) Summary K180985

Preparation Date: 05th June 2018

1.0 Submitter:

Name : Supervision Optimax Sdn Bhd
Address : Lot 38, Putra Industrial Park,
Bukit Rahman Putra,
40160 Sungai Buloh, Selangor, Malaysia.
Phone No. : 603-6145 2328
Fax No. : 603-6156 2191
Contact Person : Yap Peak Geeh
Email Address : pg.yap@supervision.com.my

2.0 Device Identification:

Proprietary Name : Aveo (omafilcon A) Soft (Hydrophilic) Contact Lenses
Common Name : Soft (Hydrophilic) Contact Lenses
Classification Name: Lenses, Soft Contact, Daily Wear
(21 CFR 886.5925, Product Code LPL)
Lenses, Soft Contact, (Disposable)
(21 CFR 886.5925, Product Code MVN)
Classification : Class II

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

	Predicate Device	
Manufacturer	CooperVision, Inc	Supervision Optimax Sdn Bhd
Device Name	Proclear (omafilcon A) Soft Contact Lenses	Aveo (omafilcon A) 1-day Aspheric Soft (Hydrophilic) Contact Lens
510(k) Number	K112302	K162223
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) Soft (Hydrophilic) Contact Lenses** are daily wear soft contact lenses 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 are 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. Reactive ultraviolet absorber RUVA-93 is used to block UV radiation.

The device is a corneal contact lens having a total diameter less than the visible iris diameter and is designed to be worn in its entirety on the cornea.

Aveo (Omafilcon A) Aspheric Soft (Hydrophilic) Contact Lenses have an aspheric front curve (external curve) which is tri-curve and spherical base curve (internal curve).

Aveo (Omafilcon A) Toric Soft (Hydrophilic) Contact Lenses have an aspheric front curve (external curve) which is tri-curve for the sphere power and multi-radius base curve for the cylinder power (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) 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.

Aveo (omafilcon A) Toric Soft (Hydrophilic) Contact Lenses are indicated the 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 between 0.50D and 2.50D or less that does not interfere with visual acuity.

Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

Frequent Planned Replacement Wear

When prescribed for frequent planned replacement wear the lenses are to be cleaned, rinsed and disinfected each time they are removed from the patients' eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lenses may be disinfected using a chemical disinfection system.

Disposable Wear

When prescribed for Daily Disposable Wear the lens is to be discarded after each removal.

6.0 Summary of the Technological Characteristics of the Device:

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

Technological Characteristics			
Characteristic	**Subject Device**	**Predicate Device**	**Predicate Device**
Product Name	Aveo	Proclear Asphere	Aveo
Manufacturer	Supervision Optimax Sdn Bhd	CooperVision, Inc.	Supervision Optimax Sdn Bhd
510(K) Number	K180985	K112302	K162223
Intended Use	**Aveo (omafilcon A) 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. **Aveo (omafilcon A) Toric Soft (Hydrophilic) Contact Lenses** are indicated the 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 between 0.50D and 2.50D or less that does not interfere with visual acuity.	**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 are myopic or hyperopic and exhibit astigmatism of 2.00D or less that does not interfere with visual acuity. **Proclear Toric (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 are myopia or hyperopic. The lens may be worn by persons who have astigmatism of 5.00D or less .	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.
Modality	Daily Wear	Daily Wear	Daily Wear
Lens Design	Aspherical	Aspherical	Aspherical
Material USAN	Omafilcon A	Omafilcon A	Omafilcon A

Name			
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	Moist Heat (Steam) in Validated Autoclave
Packaging	Blister Pack	Blister Pack	Blister Pack
Visibility Tint	Reactive Blue Dye 246	VAT Blue 6	Reactive Blue Dye 246
Water Content	59% ± 2%	59% ± 2%	59% ± 2%
Package Saline	Phosphate Buffered Saline	Phosphate Buffers PEG200 and Tween 80	Phosphate Buffered Saline
Refractive Index	1.4002	1.395 ± 0.005	1.4002
Oxygen Permeability (Dk) x 10^{-11}	25.68	21.05	25.68
Light Transmission	98%	>90%	98%
Base Curve	8.4mm to 8.8mm	8.0mm to 9.3mm	8.4mm to 8.8mm
Diameter $Ø_T$	14.0mm to 14.7mm	13.6mm to 15.2mm	14.0mm to 14.4mm
Power	-10.00 to +6.00	-20.00 to +20.00	-10.00 to +6.00

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, therefore, no clinical studies were required to demonstrate the safety or effectiveness of the subject device.

9.0 Conclusion

The Aveo (Omafilcon A) Soft (Hydrophilic) Contact Lenses are substantially equivalent to the predicate device as they are produced from the same material (Omafilcon A), have the same functional and scientific technology, lens characteristics and the intended use is identical.