September 2, 2022

Yung Sheng Optical Co., Ltd
Wen-Han Chen
RA Manager
No. 8, Keya 2nd Road, Daya District
Taichung City, 428
Taiwan

Re: K213983
Trade/Device Name: Eye Secret 59 UV Aspheric (Omafilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: July 26, 2022
Received: July 26, 2022

Dear Wen-Han Chen:

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)*
K213983

Device Name
Eye Secret 59 UV Aspheric (Omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear

Indications for Use *(Describe)*
The Eye Secret 59 UV Aspheric (Omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear is indicated for daily wear for the correction of refractive ametropia (myopia or hyperopia) in aphakic and not-aphakic persons with non-diseased eyes. The lens may be worn by person who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.
The eye care professionals may prescribe the lens for single use daily disposable or daily wear in a Frequent Replacement Program. When prescribed for frequent/planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting systems.

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

1. Type of Submission: Traditional 510(k)

2. Submitter:

Yung Sheng Optical Co., Ltd.
Address: No.8, Keya 2nd Rd., Daya District, Taichung City 42881, Taiwan
Phone: +886-4-25658384 Ext.3509
Fax: +886-4-25658387
Contact: Wen-Han Chen

Date prepared: November 24, 2021

Establishment Registration Number: 3004021238

3. Identification of the Device

Proprietary/Trade name:	Eye Secret 59 UV Aspheric (Omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
Common Name:	Contact Lens
Classification Name:	Lenses, Soft Contact, Daily Wear
Device Classification:	II
Regulation Number:	886.5925
Panel:	Ophthalmic
Product Code:	LPL for Lenses, Soft Contact, Daily Wear MVN for Lens, Contact, (Disposable)
510(k) Number:	K213983

4. Identification of the Predicate Device

Predicate Device Name:	Proclear (omafilcon A) Daily Disposable/Daily Wear Soft Contact Lens
Manufacturer:	CooperVision Inc.
Product Code:	LPL for Lenses, Soft Contact, Daily Wear MVN for Lens, Contact, (Disposable)
510(k) Number:	K061948

Predicate Device Name:	Aveo (omafilcon A) 1-Day Aspheric Soft (Hydrophilic) Contact Lenses
Manufacturer:	Supervision Optimax Sdn Bhd
Product Code:	LPL for Lenses, Soft Contact, Daily Wear MVN for Lens, Contact, (Disposable)
510(k) Number:	K162223

5. Intended Use and Indications for Use of the subject device

The Eye Secret 59 UV Aspheric (Omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear is indicated for daily wear for the correction of refractive ametropia (myopia or hyperopia) in aphakic and not-aphakic persons with non-diseased eyes. The lens may be worn by person who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

The eye care professionals may prescribe the lens for single use daily disposable or daily wear in a Frequent Replacement Program. When prescribed for frequent/planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting systems.

6. Device Description

The Eye Secret 59 UV Aspheric (Omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear is hydrophilic available with aspheric design manufactured by using Cast Molding method. The soft contact lens material, Omafilcon A, is a random copolymer of 2-hydroxyethyl methacrylate (HEMA) and 2-Methacryloyloxyethyl phosphorylcholine (MPC) crosslinked with ethylene glycol dimethacrylate (EDGMA), and has 59% water by weight. These lenses contain UV blocker, a benzotriazole UV absorbing monomer to block UV radiation. Thus, the lens helps protect against the transmission of harmful UV radiation to the cornea and into the eye. The transmittance characteristics are less than 5 % in the UVB range of 280 nm to 315 nm and less than 50 % in the UVA range of 316 nm to 380 nm. The lenses are tinted from edge to edge for visibility purposes with the color additive Reactive Blue 246.

The Eye Secret 59 UV Aspheric (Omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear helps protect against transmission of harmful UV radiation to the cornea and into the eye.

The lenses are available as aspheric lenses. Each finished lens is supplied in a plastic blister container with a sterile isotonic phosphate buffered saline solution containing 2-(Methacryloyloxy) ethyl 2-(trimethylammonio) ethyl phosphate-n-butylmethacrylate copolymer (PMB) wetting agent.

7. Characteristics of Substantial Equivalence

- Material and Process Comparison Table

Device Name	Subject Device Eye Secret 59 UV Aspheric (Omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear	Predicate device Proclear (omafilcon A) Daily Disposable/Daily Wear Soft Contact Lens	Predicate device Aveo (omafilcon A) 1-Day Aspheric Soft (Hydrophilic) Contact Lenses
Manufacturer	Yung Sheng Optical Co., ltd	CooperVision, Inc.	Supervision Optimax Sdn Bhd
510(k) Number	This submission	K061948	K162223
FDA Category	Group II Non-ionic High water content	Group II Non-ionic High water content	Group II Non-ionic High water content
Product Code	LPL and MVN	LPL and MVN	LPL and MVN
Intended Use	The Eye Secret 59 UV Aspheric (Omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear is indicated for daily wear for the correction of refractive ametropia (myopia or hyperopia) in aphakic and not-aphakic persons with non-diseased eyes. The lens may be worn by person who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.	Proclear (omafilcon A) Daily Disposable/Daily Wear Soft Contact Lens 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 2.00D or less that does not interfere with visual acuity.	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 orhyperopic 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.
Material USAN Name	Omafilcon A	Omafilcon A	Omafilcon A
Manufacturing Method	Cast Molded	Cast Molded	Cast Molded
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
Water Content	59 ± 2 %	60 ± 2 %	59 ± 2 %
Tint	Reactive Blue 246	Vat Blue 6	Reactive Blue 246
Packaging solution	Phosphate buffered saline solution containing 2-(Methacryloyloxy) ethyl 2-(trimethylammonio) ethyl phosphate-n-butylmethacrylate copolymer wetting agent	Not Stated	Phosphate Buffered Saline

- Technological Characteristics Comparison Table

Device Name	Subject Device Eye Secret 59 UV Aspheric (Omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear	Predicate device Proclear (omafilcon A) Daily Disposable/Daily Wear Soft Contact Lens	Predicate device Aveo (omafilcon A) 1-Day Aspheric Soft (Hydrophilic) Contact Lenses
Base Curve	7.50 ~ 9.00 ± 0.20 mm	8.00 ~ 9.50 ± 0.20 mm	8.40 ~ 8.80 ± 0.20 mm
Diameter	12.0 ~ 15.0 ± 0.20 mm	13.0 ~ 15.5 ± 0.20 mm	14.0 ~ 14.4 ± 0.20 mm
Center Thickness	0.030 ~ 0.200 mm	0.035 ~ 0.960 mm	Not Stated
Refractive Index	1.390 ± 0.005 n_d	1.400 ± 0.005 n_d	1.4002 ± 0.005 n_d
Oxygen Permeability (Dk) x 10^{-11} (cm^2/sec) (ml O_2/ml x mmHg)	25 ± 20%	21.00 ± 20 %	25.68 ± 20 %
Light Transmittance	95 ± 5 %	> 90%	98 %
UV-A	< 50 %	Not Stated	Not Stated
UV-B	< 5 %	Not Stated	Not Stated
Powers	-20.00 ~ +20.00 D	-20.00 ~ +20.00 D	-10.00 ~ +6.00 D

8. Non-Clinical Testing

A series of preclinical testing were performed to demonstrate the safety and effectiveness of the Eye Secret 59 UV Aspheric (Omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear.

- Physiochemical Studies

  The physiochemical studies were conducted according to ISO 18369-4:2017 Ophthalmic Optics-Contact Lenses-Part 4: Physiochemical properties of contact lens materials and ISO 18369-3:2017 Ophthalmic Optic-Contact Lenses-Part 3: Measurement methods. The physical, optical and chemical properties of the lens are within established specifications for the lenses. The following tests were conducted as recommended by the FDA Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses, 1994:

  - Finished Lens Parameters
  - Refractive Index
  - Light Transmittance
  - Water Content
  - Extractables (Leachability)
  - Oxygen Permeability
  - Mechanical Properties Testing
  - Physical Compatibility Test with Packaging Solution
  - Shelf-life

- Toxicology Studies

  Toxicology studies reports show that the lenses are non-toxic and biocompatible with the ocular environment.

Eye Secret 59 UV Aspheric (Omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
● Cytotoxicity Test (ISO 10993-5) ● Ocular Irritation Test (ISO 10993-10) ● Acute Systemic Toxicity Test (ISO 10993-11) ● Skin Sensitization Test (ISO 10993-10)
Packaging Solution
● Cytotoxicity Test (ISO 10993-5) ● Ocular Irritation Test (ISO 10993-10) ● Acute Systemic Toxicity Test (ISO 10993-11)
PP blister and aluminum foil (which is identical to that cleared under K132854)
● Cytotoxicity Test (ISO 10993-5) ● Ocular Irritation Test (ISO 10993-10) ● Acute Systemic Toxicity Test (ISO 10993-11)

The results of the non-clinical testing, including physiochemical studies and toxicology studies, demonstrated that Eye Secret 59 UV Aspheric (Omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear which met all the specifications is substantially equivalent to the safety and effectiveness of both predicate devices.

9. Summary of Clinical Study

The technological characteristics, formulation, manufacturing and sterilization processes are the same as the predicate devices. Therefore, no clinical studies were required to demonstrate the safety or effectiveness of the subject device.

10. Conclusion

The Eye Secret 59 UV Aspheric (Omafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear is substantially equivalent to the predicate devices, Proclear (Omafilcon A) Daily Disposable/Daily Wear Soft Contact Lens (K061948) and Aveo (Omafilcon A) 1-Day Aspheric Soft (Hydrophilic) Contact Lenses (K162223)

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 as well as the intended uses are identical. It is concluded that the lenses are as safe, as effective and perform as well as the both predicate devices.