December 16, 2024

Yung Sheng Optical Co., Ltd.
Wen-Han Chen
RA Manager
No. 8, Keya 2nd Road, Daya District
Taichung City, 42881
Taiwan

Re: K232839
Trade/Device Name: Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear, Air Light 38 UV Aspheric (polymacon) 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: November 15, 2024
Received: November 15, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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)*
K232839

Device Name
Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear,
Air Light 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear

Indications for Use *(Describe)*
The Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear/Air Light 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear is available as aspheric lens design and indicated 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.

FREQUENT/PLANNED REPLACEMENT WEAR
When prescribed for Frequent/Planned Replacement Wear, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting system each time it is removed and should be discarded per the eye care practitioner's guidance.

DISPOSABLE WEAR
When prescribed for 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

1. Type of Submission: Traditional 510(k) 510(k) number: K232839

2. Submitter: Yung Sheng Optical Co., Ltd.
Address: No.8, Keya 2nd Rd., Daya District, Taichung City 42881, Taiwan
Establishment Registration Number: 3004021238
Date prepared: May 26, 2023
Contact Person 1
Name: Mr. Wen-Han, Chen / RA manager
Phone number: +886-4-25658384 #3509
E-mail: wenhanchen@hydron.com.tw
Contact Person 2
Name: Mr. James Chang / RA specialist
Phone number: +886-4-25658384 #3514
E-mail: jameschang@hydron.com.tw

3. Identification of the Device

Device name:	Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear, Air Light 38 UV Aspheric (polymacon) 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)

4. Identification of the Predicate Device

Predicate Device Name:	Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear
Manufacturer:	Yung Sheng Optical Co., Ltd.
Product Code:	LPL for Lenses, Soft Contact, Daily Wear MVN for Lens, Contact, (Disposable)
510(k) Number:	K150630

Predicate Device Name:	Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses, Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses
Manufacturer:	Pegavision Corporation
Product Code:	LPL, MVN
510(k) Number:	K211448

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

The **Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear/Air Light 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear** is available as aspheric lens design and indicated 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.

FREQUENT/PLANNED REPLACEMENT WEAR

When prescribed for Frequent/Planned Replacement Wear, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting system each time it is removed and should be discarded per the eye care practitioner's guidance.

DISPOSABLE WEAR

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

6. Device Description

The **Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear/Air Light 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear** is available as aspheric lens design. The lens material, polymacon, is a random copolymer of 2-hydroxyethyl methacrylate

(HEMA) crosslinked with ethylene glycol dimethacrylate (EGDMA). The lenses contain a benzophenone UV-absorbing monomer which has been incorporated into the polymer matrix of the lens to absorb ultraviolet (UV) light. The lenses are clear or tinted from edge to edge for visibility purposes with the color additive C.I. Reactive Blue No. 4. Each finished lens is supplied in a plastic blister container with A) Standard Saline Solution, or B) Sodium Hyaluronate Packaging Solution, or C) PMB Packaging Solution, or D) Cyanocobalamin Packaging Solution.

The purpose of this 510(k) Notification is to notify the FDA of a new device, intended for commercial distribution by Yung Sheng Optical Co., Ltd. under the trade name of **Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear/Air Light 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear** containing 4 different type of packaging solution.

7. Characteristics of Substantial Equivalence

- Material and Process Comparison Table

	Subject Device	Predicate device	
Device Name	Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear/Air Light 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear	Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear	Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses, Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses
Manufacturer	Yung Sheng Optical Co., ltd	Same	Pegavision Corporation
510(k) Number	K232839	K150630	K211448
Classification	Class II	Same	Same
Product Code	LPL and MVN	Same	Same
Intended Use	The Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear/Air Light 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear is available as aspheric lens design and indicated 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. **FREQUENT/PLANNED REPLACEMENT WEAR** When prescribed for Frequent/Planned Replacement Wear, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting system each time it is	The Eye Secret 38 UV is indicated for the correction of refractive ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by person who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The Eye Secret 38 UV helps protect against transmission of harmful UV radiation to the cornea and into the eye. The eye care professionals may prescribe the lens for single use daily disposable or daily wear in a Frequent Replacement Program. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide	**Spherical and Aspherical** Aquamax (Etafilcon A) SPHERE and ASPHERE Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseases eyes in powers from +6.00 to -12.00 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** Aquamax (Etafilcon A) Toric Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +6.00 to -12.25 diopters and astigmatic corrections from -0.25 to -3.50 diopters. **Multifocal** Aquamax (Etafilcon A) Multifocal Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and/or non-aphakic persons with non-diseased eyes in powers

Device Name	Subject Device	Predicate device	
	Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear/Air Light 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear	Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear	Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses, Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses
	removed and should be discarded per the eye care practitioner's guidance. **DISPOSABLE WEAR** When prescribed for Disposable Wear, the lens is to be discarded after each removal.	disinfecting systems.	from +6.00 to -12.25 diopters and with non-diseased eyes who may require a reading addition from +0.25D to +3.00D. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The lenses are intended for frequent/planned replacement wear with cleaning, rinsing, disinfection and scheduled replacement as prescribed by the eye care professional. When prescribed for frequent/planned replacement wear, the lens maybe disinfected using a chemical (not heat) lens care system only.
Material **USAN Name**	Polymacon	Same	Etafilcon A
Manufacturing Method	Cast Molded	Same	Same
Sterilization	Moist Heat (Steam) in Validated Autoclave	Same	Same
Packaging	Blister pack	Same	Same
Water Content	38 %	Same	58%
Tint	C.I. Reactive Blue #4	Same	Reactive Blue 19
Packaging solution	A) Standard Saline Solution, or B) Sodium Hyaluronate Packaging Solution, or C) PMB Packaging Solution, or D) Cyanocobalamin Packaging Solution.	Phosphate buffered saline solution containing sodium hyaluronate and trehalose.	Sterile isotonic borate buffered saline solution with Tween 80, Sodium Hyaluronate, Polyethylene Glycol, and Cyanocobalamin.

- Technological Characteristics Comparison Table

Device Name	Subject Device		Predicate device	
	Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear/Air Light 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear		Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear	Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses, Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses
Base Curve	7.85 ~ 10.00 mm		7.50 ~ 9.00 mm	N/A
Diameter	12.0 ~ 15.0 mm		Same	N/A
Center Thickness	Eye Secret 38 UV lens	0.06 ~ 0.13 mm	0.04 ~ 0.14 mm	N/A
	Air Light 38 UV lens	0.03 mm		
Refractive Index	1.440 ± 0.005 n_d		Same	1.402 n_d
Oxygen Permeability (Dk)	13.5 x 10^{-11} (cm^2/sec)(ml O_2/ml x mmHg)		Same	19.73 x 10^{-11} (cm^2/sec)(ml O_2/ml x mmHg)
Light Transmittance	95 ± 5 %		Same	> 95%
UV-A Transmittance	Eye Secret 38 UV lens	< 50 %	Same	Same
	Air Light 38 UV lens	< 70%		
UV-B Transmittance	Eye Secret 38 UV lens	< 5 %	Same	Same
	Air Light 38 UV lens	< 40%		
Powers	Eye Secret 38 UV lens	-20.00 ~ +20.00 D	-0.50 ~ -20.00 D	-12.00 ~ +6.00
	Air Light 38 UV lens	0.00 ~ -10.00 D		

8. Non-Clinical Testing

A series of preclinical testing were performed to demonstrate the safety and effectiveness of the Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear/Air Light 38 UV Aspheric (polymacon) 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 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear
• Cytotoxicity Test (ISO 10993-5) • Ocular Irritation Test (ISO 10993-10, ISO 9394) • Acute Systemic Toxicity Test (ISO 10993-11)
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 *[identical to K150630]*
● Cytotoxicity Test (ISO 10993-5) ● Ocular Irritation Test (ISO 10993-10) ● Acute Systemic Toxicity Test (ISO 10993-11)

The biocompatibility tests were conducted on test articles representative of the primary packaging solution options. The results of the non-clinical testing, including physiochemical studies and toxicology studies, demonstrated that the Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear/Air Light 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear met all the specifications and is concluded substantially equivalent to the predicate device.

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 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear/Air Light 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear is substantially equivalent to the predicate devices, Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear (510K number K150630) and Aquamax (Etafilcon A) Daily Disposable Soft (Hydrophilic) Contact Lenses, Aquamax (Etafilcon A) Soft (Hydrophilic) Contact Lenses (510K number K211448) in term of optical property, physiochemical and pre-clinical toxicology. They are produced from the same or similar material, 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.