September 25, 2025

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

Re: K244009

Trade/Device Name: Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear (Daily Wear); Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens (Daily Disposable)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: December 25, 2024
Received: August 18, 2025

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K244009

Please provide the device trade name(s).

Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear (Daily Wear);
Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens (Daily Disposable)

Please provide your Indications for Use below.

The Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear and Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens are 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 reusable daily wear in a Frequent Replacement Program.

DISPOSABLE WEAR:

When prescribed for Disposable Wear, the Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens is to be discarded after each removal.

FREQUENT/PLANNED REPLACEMENT WEAR:

When prescribed for Frequent/Planned Replacement Wear, the Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

1. Type of Submission Traditional 510(k)

2. Submitter

Manufacturer:	Yung Sheng Optical Co., Ltd.
Address:	No.8, Keya 2nd Rd., Daya District, Taichung City 42881, Taiwan
Phone:	+886-4-25658384 Ext.3514
Fax:	+886-4-25658387
Contact:	James Chang
Date prepared:	December 25, 2024
Establishment Registration Number:	3004021238

3. Identification of the Device

Proprietary/Trade name:	Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear, Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens
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:	Pure Plus UV Aspheric (Otufilcon A) Silicone 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:	K223585

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

The Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear and Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens are 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 reusable daily wear in a Frequent Replacement Program.

DISPOSABLE WEAR:

When prescribed for Disposable Wear, the Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens is to be discarded after each removal.

FREQUENT/PLANNED REPLACEMENT WEAR:

When prescribed for Frequent/Planned Replacement Wear, the Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear 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.

6. Device Description

The Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear and Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens are hydrophilic available with aspheric design manufactured by using Cast Molding method. The soft contact lens material, Otufilcon A, which is a copolymer of silicone-containing monomers and hydrophilic monomers, and has 44% 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 315 nm to 380 nm. The lenses are tinted from edge to edge for visibility purposes with the color additive. The lens is marked with wording "321" to help user better distinguish the correct side before inserting in eyes.

The lenses are available as aspheric lenses. Each finished lens is supplied in a plastic blister container with A) PMB Packaging Solution, or B) Cyanocobalamin Packaging Solution depends on customer's requirement.

7. Characteristics of Substantial Equivalence

- Material and Process Comparison Table

	Subject Device	Predicate device
Device Name	Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear, Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens	Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear
Manufacturer	Yung Sheng Optical Co., ltd	Yung Sheng Optical Co., ltd
510(k) Number	This submission	K223585
FDA Category	Group V	Group V
Product Code	LPL and MVN	LPL and MVN
Intended Use	The Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear and Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens are 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 reusable daily wear in a Frequent Replacement Program. **DISPOSABLE WEAR:** When prescribed for Disposable Wear, the Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens is to be discarded after each removal. **FREQUENT/PLANNED REPLACEMENT WEAR:** When prescribed for Frequent/Planned Replacement Wear, the Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear 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.	The Pure Plus UV Aspheric (Otufilcon A) Silicone 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. The Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear is daily disposable single use and should be discarded after removal.
Material **USAN Name**	Otufilcon A	Otufilcon A
Manufacturing Method	Cast Molded	Cast Molded
Curing	Thermal Cure	Thermal Cure

	Subject Device	Predicate device
Device Name	Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear, Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens	Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear
Sterilization	Moist Heat (Steam) in Validated Autoclave	Moist Heat (Steam) in Validated Autoclave
Packaging	Blister pack	Blister pack
Water Content	44 %	44 %
Tint	Reactive Blue 246	Reactive Blue 246
Packaging solution	Sterile A) PMB Packaging Solution, or B) Cyanocobalamin Packaging Solution.	Sterile isotonic phosphate buffered saline containing PMB wetting agents

- Technological Characteristics Comparison Table

	Subject Device	Predicate device
Device Name	Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear, Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens	Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear
Base Curve	7.50 ~ 9.00 mm	7.50 ~ 9.00 mm
Diameter	12.0 ~ 15.0 mm	12.0 ~ 15.0 mm
Center Thickness	0.04 ~ 0.14 mm	0.04 ~ 0.14 mm
Refractive Index	1.417 ± 0.005 n_d	1.417 ± 0.005 n_d
Oxygen Permeability (Dk)	120 x 10^{-11} (cm^2/sec) (ml O_2/ml x mmHg)	120 x 10^{-11} (cm^2/sec) (ml O_2/ml x mmHg)
Light Transmittance	95 %	95 %
UV-A	< 50 %	< 50 %
UV-B	< 5 %	< 5 %
Powers	-20.00 ~ +20.00 D	-20.00 ~ +20.00 D

8. Non-Clinical Testing

A series of preclinical testing were performed to demonstrate the safety and effectiveness of the Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear and Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens.

- 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.

Pure Plus UV Aspheric (Otufilcon A) Silicone 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) • 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
• 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 Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear and Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens which met all the specifications and are concluded substantially equivalent to the safety and effectiveness of predicate device.

9. Summary of Clinical Study

Clinical data was not needed to support the safety and effectiveness of the subject device since Otufilcon A is an existing USAN material that was previously cleared in K223585.

10. Conclusion

The Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear and Pure Plus UV Aspheric (Otufilcon A) 1-Day Silicone Soft (hydrophilic) Contact Lens are substantially equivalent to the predicate devices, Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear (K223585) in term of optical property, physiochemical and pre-clinical toxicology. They are produced from the same material (Silicone marcomer), 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.