



December 20, 2023

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

Re: K223585

Trade/Device Name: Pure Plus UV Aspheric (Otufilecon A) Silicone 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 17, 2023

Received: November 17, 2023

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.

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

Indications for Use

510(k) Number (if known)
K223585

Device Name
Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear

Indications for Use (Describe)

The Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear is 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 practitioners may prescribe the contact 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 discard after 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.

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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.3514
Fax: +886-4-25658387
Contact: James Chang
Date prepared: November 30, 2022
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
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: Bausch + Lomb Ultra® (Samfilcon A) Contact Lens
Manufacturer: Bausch & Lomb, Inc.
Product Code: LPL for Lenses, Soft Contact, Daily Wear
MVN for Lens, Contact, (Disposable)
510(k) Number: K131208

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 is 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. 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.

6. Device Description

The Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear is hydrophilic available with aspheric design manufactured by using Cast Molding method. The soft contact lens material, Otufilcon A, which is a random 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 Pure Plus UV Aspheric (Otufilcon A) Silicone 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 wetting agent.

7. Characteristics of Substantial Equivalence

- Material and Process Comparison Table

Device Name	Subject Device	Predicate device
	Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear	Bausch + Lomb Ultra® (Samfilcon A) Contact Lens
Manufacturer	Yung Sheng Optical Co., Ltd	Bausch & Lomb, Inc.
510(k) Number	This submission	K131208
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 is 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. 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.	Bausch + Lomb Ultra® (Samfilcon A) Contact Lens are designed for the intended use to be worn, directly against the cornea and adjacent limb and sclera areas of the eyes to correct vision conditions.
Material USAN Name	Otufilcon A	Samfilcon A
Manufacturing Method	Cast Molded	Cast Molded
Sterilization	Moist Heat (Steam) in Validated Autoclave	Moist Heat (Steam) in Validated Autoclave
Packaging	Blister pack	Blister pack
Water Content	44 %	46 %
Tint	Reactive Blue 246	Reactive Blue 246
Packaging solution	Sterile isotonic phosphate buffered saline containing wetting agents.	Sterile borate buffered saline with poloxamine solution

● Technological Characteristics Comparison Table

Device Name	Subject Device	Predicate device
	Pure Plus UV Aspheric (Otufilcon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear	Bausch + Lomb Ultra® (Samfilcon A) Contact Lens
Base Curve	7.50 ~ 9.00 mm	7.80 ~ 9.50 mm
Diameter	12.0 ~ 15.0 mm	13.5 ~ 15.0 mm
Center Thickness	0.04 ~ 0.14 mm	0.05 ~ 0.50 mm
Refractive Index	1.417 ± 0.005 n _d	1.411 n _d
Oxygen Permeability (Dk)	120 x 10 ⁻¹¹ (cm ² /sec)(ml O ₂ /ml x mmHg)	114 x 10 ⁻¹¹ (cm ² /sec)(ml O ₂ /ml x mmHg)
Light Transmittance	95 %	97.3 %
UV-A	< 50 %	Not Stated
UV-B	< 5 %	Not Stated
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.

- **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 which met all the specifications and is concluded substantially equivalent to the safety and effectiveness of predicate device.

9. Summary of Clinical Study

A prospective, randomized, double-blind, parallel, active-controlled clinical study with 3 months treatment follow-up was completed. The location of Clinical Study is in Taiwan, where is outside of United States only. The study screened 151 subjects and 7 subjects failed to be included. A total of 144 subjects were randomized and enrolled in this study (73 subjects wore the test lenses [test group] and 71 subjects wore control lenses “Bausch Lomb Ultra Contact Lens” [control group]. Of the 144 randomized subjects, 5 subjects (3 subjects in the test group and 2 subjects in the control group) were withdrawn and 139 subjects (70 subjects in the test group and 69 subjects in the control group) completed the study.

Regarding the primary efficacy endpoint, the effectiveness of corrected visual acuity is at 3-month. Effectiveness is defined as visual acuities of both eyes correctable to ≥ 1.0 with contact lens. Effectiveness formula (%) is total number of subjects with vision correction of ≥ 1.0 at a given timepoint / total number of subjects enrolled at a given time x 100%. Definition of total number of subjects enrolled at a given time is the total number of subjects conforming to the PPS criteria and having worn lenses for 3 months. Based on the test results, the efficacy endpoints showed that the test group was non-inferior to the control group. Moreover, the lenses in both groups were effective in vision correction and did not cause unwanted diopter changes in spherical or cylindrical power and corneal astigmatism.

In safety endpoints, the incidence of adverse events was not higher than in the control group and the ocular conditions remained normal at the end of the study. No unpredictable side effects were observed during the trial.

Therefore, this clinical investigation supports the claim of substantial equivalence between the two lens types with regard to clinical safety and effectiveness.

10. Conclusion

The Pure Plus UV Aspheric (Otufilecon A) Silicone Soft (hydrophilic) Contact Lens for Daily Wear is substantially equivalent to the predicate devices,

Bausch + Lomb Ultra® (Samfilcon A) Contact Lens (510K number K131208) 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.