October 28, 2026

St. Shine Optical Co., Ltd.
Mina Lee
Project Manager
4,5f # 276-2, Sec. 1, Ta Tung Rd.,Hsi Chih Dist.
New Taipei City, 22146
Taiwan

Re: K260311
Trade/Device Name: Saview 60 UV (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens; Saview 60 UV toric (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens; Saview 60 UV multifocal (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: September 22, 2026
Received: September 22, 2026

Dear Mina Lee:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260311

Please provide the device trade name(s).

Saview 60 UV (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens;
Saview 60 UV toric (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens;
Saview 60 UV multifocal (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens

Please provide your Indications for Use below.

Saview 60 UV (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1.00D of astigmatism or less does not interfere with visual acuity.

Saview 60 UV toric (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic or not-aphakic persons with non-diseased eyes. The toric lens is specified for up to 3.00 diopters of astigmatism. The highest cylinder power is -3.00D.

Saview 60 UV multifocal (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less does not interfere with visual acuity. The multifocal lens is specified for up to +3.00 diopters of add power. The highest add power is +3.00D.

Saview 60 UV, Saview 60 UV toric, and Saview 60 UV multifocal (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens is daily disposable wear or frequent replacement wear. Eye care practitioners may prescribe the lens for daily disposable wear, or for frequent replacement wear.

For a daily disposable wear lens, the lens may be prescribed for single-use daily disposable wear and not intended to be cleaned or disinfected and should be discarded after a single use.

For a frequent replacement wear lens, the lens may be cleaned or disinfected using chemicals disinfecting systems (hydrogen peroxide disinfecting systems are not included).

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

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

5.1 Submitter Information:

Address:	St. Shine Optical Co., Ltd. 4,5F No. 276-2, Sec. l, Ta Tung Rd. Hsi Chih Dist., 22146, New Taipei City Taiwan R.O.C.
Registration No.:	9617499
Contact Person:	Mina Lee Assistant, R&D Div.
E-mail:	s7034@stshine.com.tw Telephone:
Telephone:	886-2-2641-7543#228
Fax:	886-8691-6776
Date Prepared:	January 26, 2026

5.2 Device:

Common Name:	Soft (Hydrophilic) Contact Lens
Trade/Proprietary Name:	Saview 60 UV (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens Saview 60 UV toric (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens Saview 60 UV multifocal (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens
Classification Name:	Soft (Hydrophilic) Contact Lens(daily wear)
Device Classification:	Class II (21 CFR 886.5925)
Product Code:	LPL, MVN
Panel:	Ophthalmic

5.3 Predicate Devices:

- PROCLEAR (OMAFILCON A) DAILY DISPOSABLE/DAILY WEAR SOFT CONTACT LENS – K061948
- Saview SH 38 UV, Saview SH 38 UV toric, Saview SH 38 UV multifocal (Senofilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens – K240477
- Saview SH Optic 38 UV, Saview SH Optic 38 UV toric, Saview SH Optic 38 UV multifocal (Senofilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens– K250364

5.4 Description of Devices:

Saview 60 UV, Saview 60 UV toric, Saview 60 UV multifocal (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens:

- The lens designs include spherical, toric and multifocal lenses.
- UV absorbing monomer is used. The transmittance is less than 5% in the UVB range of 280-315nm and less than 50% in the UVA range of 316-380nm.
- Tinted blue [Phthalocyaninato(2-)] copper in color additives approved in 21 CFR Part 74 for use in medical devices are used.
- The lens contains 60% water by weight and each lens is supplied sterile in a blister container in saline solution.

5.5 Indication for Use:

Saview 60 UV (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1.00D of astigmatism or less does not interfere with visual acuity.

Saview 60 UV toric (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic or not-aphakic persons with non-diseased eyes. The toric lens is specified for up to 3.00 diopters of astigmatism. The highest cylinder power is -3.00D.

Saview 60 UV multifocal (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less does not interfere with visual acuity. The multifocal lens is specified for up to +3.00 diopters of add power. The highest add power is +3.00D.

Saview 60 UV, Saview 60 UV toric, and Saview 60 UV multifocal (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens is daily disposable wear or frequent replacement wear. Eye care practitioners may prescribe the lens for daily disposable

wear, or for frequent replacement wear.

For a daily disposable wear lens, the lens may be prescribed for single-use daily disposable wear and not intended to be cleaned or disinfected and should be discarded after a single use.

For a frequent replacement wear lens, the lens may be cleaned or disinfected using chemicals disinfecting systems (hydrogen peroxide disinfecting systems are not included).

5.6 Comparison of technological characteristics with the predicate device

	Subject Device	**Predicate Device**	**Predicate Device**	**Predicate Device**
Device	Saview 60 UV, Saview 60 UV toric, Saview 60 UV multifocal (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens	PROCLEAR (OMAFILCON A) DAILY DISPOSABLE/DAILY WEAR SOFT CONTACT LENS (K061948)	Saview SH 38 UV, Saview SH 38 UV toric, Saview SH 38 UV multifocal (Senofilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens (K240477)	Saview SH Optic 38 UV, Saview SH Optic 38 UV toric, Saview SH Optic 38 UV multifocal (Senofilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens (K250364)
Intended Use	**Sphere:** Daily wear for the correction of refractive ametropia (myopia, hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1.00D of astigmatism or less does not interfere with visual acuity.	**Sphere:** Daily wear for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 2.00D of astigmatism or less.	**Sphere:** Daily wear for the correction of refractive ametropia (myopia, hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1.00D of astigmatism or less does not interfere with visual acuity.	**Sphere:** Daily wear for the correction of refractive ametropia (myopia, hyperopia) in aphakic or not-aphakic persons with non-diseased eyes who may have 1.00D of astigmatism or less does not interfere with visual acuity.

	Toric: Daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic or not-aphakic persons with non-diseased eyes. The toric lens is specified for up to 3.00 diopters of astigmatism. The highest cylinder power is -3.00D.	**Toric:** Daily wear for the correction of visual acuity in phakic or aphakic persons with non-diseased eyes that are hyperopic or myopic and may have 5.00D of astigmatism or less.	**Toric:** Daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic or not-aphakic persons with non-diseased eyes. The toric lens is specified for up to 3.00 diopters of astigmatism. The highest cylinder power is -3.00D.	**Toric:** Daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic or not-aphakic persons with non-diseased eyes. The toric lens is specified for up to 3.00 diopters of astigmatism. The highest cylinder power is -3.00D.
	Multifocal: Daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less does not interfere with visual acuity. The multifocal lens is specified for up to +3.00 diopters of add power. The highest add power is +3.00D.	**Multifocal:** Daily wear for the correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 2.00D of astigmatism or less.	**Multifocal:** Daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less does not interfere with visual acuity. The multifocal lens is specified for up to +3.00 diopters of add power. The highest add power is +3.00D.	**Multifocal:** Daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less does not interfere with visual acuity. The multifocal lens is specified for up to +3.00 diopters of add power. The highest add power is +3.00D.
Modality	Daily disposable and frequent replacement wear	Daily disposable replacement wear	Daily disposable and frequent replacement wear	Daily disposable replacement wear
Material (Classification)	Group II Non-Ionic High Water Content	Group II Non-Ionic High Water Content	Group 5C (Silicone hydrogel: low water subgroup)	Group 5C (Silicone hydrogel: low water subgroup)
USAN Name	Omafilcon A	Omafilcon A	Senofilcon A	Senofilcon A
Indication for use	Myopia, hyperopia, presbyopia, astigmatism	Myopia, hyperopia, presbyopia, astigmatisn	Myopia, hyperopia, presbyopia, astigmatism	Myopia, hyperopia, presbyopia, astigmatism
Water content	60%	60±2%	38%	38%
Visible light transmittance	≧90%	>90%	≧90%	≧90%

UV transmittance	UVB <5% UVA <50%	UVB<1% UVA <10%	UVB <5% UVA <50%	UVB <5% UVA <50%
Dk(35°C) non-edge corrected	28 x 10^{-11}	N/A	122 x 10^{-11}	122 x 10^{-11}
Dk(35°C) boundary layer and edge corrected	25 x 10^{-11}	25 x 10^{-11}	103 x 10^{-11}	103 x 10^{-11}
Power	+20.00 to -20.00D Cylinder power: -0.50 to -3.00D (for toric only) Continuous add power to +3.00D (for multifocal only)	20.00 to -20.00D Cylinder power: -0.50 D to -10.00D as applicable Continuous add power +0.25D to +5.00D as applicable	+20.00 to -20.00D Cylinder power: -0.50 to -3.00D (for toric only) Continuous add power to +3.00D (for multifocal only	+20.00 to -20.00D Cylinder power: -0.50 to -3.00D (for toric only) Continuous add power to +3.00D (for multifocal only
Color	Tint: [Phthalocyaninato(2-)] copper	Tint: Vat Blue 6	Tint: [Phthalocyaninato(2-)] copper	Tint: [Phthalocyaninato(2-)] copper
Refractive index	1.40	1.40	1.42	1.42
Method of manufacture	Moulded	Cast Molded	Moulded	Moulded
Packaging materials	PP (Polypropylene) blister and Aluminum foil	Blister Pack	PP (Polypropylene) blister and Aluminum foil	PP (Polypropylene) blister and Aluminum foil
Package storage saline solution	Saline solution	N/A	Saline solution	Saline solution with PEG

5.7 Summary of Non-clinical Performance Data

All tests were performed to assess the properties and safety and effectiveness of the contact lens following the 1994 FDA Guidance Document for Daily Wear Contact Lenses. Biocompatibility tests were conducted in accordance with the GLP regulation (21 CFR Part 58). All other testing was conducted according to scientific methods. Non-Clinical testing performed includes:

Physicochemical Properties:

- Physical Compatibility of Contact Lens Care Products with Contact Physical Compatibility of Contact Lens Care Products with Contact

−Extractables

−Finished Lens Parameters

−Transmittance

−Refractive Index

−Water Content

−Oxygen Permeability

−Mechanical Properties (Modulus, Tensile strength, Elongation, Toughness)

−Leachable Additives

−Specific Gravity

Test results demonstrated that subject device complies with ISO 11981:2017, ISO 18369-2:2017, ISO 18369-3:2017, 18369-4:2017, FDA Guidance- Preparing a Color Additive Petition for Submission to the Center for Food Safety and Applied Nutrition for Color Additives Used in or on Contact Lenses (2006/05) requirements.

Sterilization validation and Shelf life:

−Stability Test

−Autoclave Validation

−Report of Evaluation for the Sterilization Efficacy of BI Inside and Outside of the Package

−Sterility Test Report

−Bioburden test

−Clean Environment Test Controls Report

Test results demonstrated that subject device complies with ISO 17665-1:2006, USP<71>, ISO 11737-1:2018, ISO 11737-2:2019, USP<61>, ISO 11987:2012, ISO 18369-1:2017, ISO 18369-2:2017, ISO 18369-3:2017, ISO 18369-4:2017, ISO 14644-1:2015, ISO 14644-3:2019, NEBB: 2009 requirements.

Biocompatibility:
For lens:

−Cytotoxicity (ISO 10993-5:2009)

−Ocular Irritation (ISO 10993-23:2021)

−Acute Systemic Injection (ISO10993-11:2017)

For packaging solution:
The material of packaging solution is identical with K240477 saline solution.

For packaging material:
The material of blister package comprises a base and a cover. The base material is homo PP (Polypropylene) and the cover is a laminate of Aluminum foil. Therefore, all packaging materials including the base and the cover are identical with K250364.

The testing performed on Saview 60 UV (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens, Saview 60 UV toric (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens, Saview 60 UV multifocal (Omafilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens demonstrated that the device functions in a safe and effective manner. Performance tests included conformance to specifications, functional test results verify that the device performs as expected and are equivalent to the predicate device without creating additional risk to the user.

5.8 Summary of Clinical Performance Data

No clinical test data was used to support the decision of substantial equivalence. The safety and effectiveness of finished contact lenses have been established through previous non-clinical performance testing. Safety and effectiveness of the

Omafilcon A lens material is identical with K061948. Safety and effectiveness of packaging material is identical with K250364. Package storage saline solution is identical with K240477.

5.9 Substantial Equivalence Conclusion:

The information submitted in the 510(k) establishes that the Saview 60 UV lenses have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Method of manufacture Shelf life testing has shown the lenses remain sterile and that lens properties do not change before the expiration date. Results of cytotoxicity, ocular irritation and acute systemic injection tests showed substantially equivalent to the predicate device in safety and biocompatibility. Therefore, the Saview 60 UV, Saview 60 UV toric, Saview 60 UV multifocal (Omafilcon A) Soft (Hydrophilic) Contact Lens are substantially equivalent to the predicate devices.