July 1, 2024

St. shine Optical Co., Ltd.
Mina Lee
R&D assistant person
4,5F No. 276-2, Sec. 1, Ta Tung Rd.,Hsi Chih Dist.
New Taipei City, 22146
Taiwan

Re: K240477
Trade/Device Name: Saview SH 38 UV (Senofilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens; Saview SH 38 UV toric (Senofilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens; Saview SH 38 UV multifocal (Senofilcon 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: May 20, 2024
Received: May 20, 2024

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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents titled "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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240477

Device Name

Saview SH 38 UV (Senofilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens;
Saview SH 38 UV toric (Senofilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens;
Saview SH 38 UV multifocal (Senofilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens

Indications for Use *(Describe)*

Saview SH 38 UV (Senofilcon 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 SH 38 UV toric (Senofilcon 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 SH 38 UV multifocal (Senofilcon 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 SH 38 UV, Saview SH 38 UV toric, and Saview SH 38 UV multifocal (Senofilcon 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).

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.

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: Febuary 05, 2024

Device:

Common Name:	Soft (Hydrophilic) Contact Lens
Trade/Proprietary Name:	Saview SH 38 UV (Senofilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens Saview SH 38 UV toric (Senofilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens Saview SH 38 UV multifocal (Senofilcon 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

Predicate Devices:

- VISTAKON (SENOFILCON A) SOFT CONTACT LENS - K042275
- 55 UV, 55 UV Multifocal, and the 55 UV Toric (methafilcon A) Soft (Hydrophilic) Daily Wear Contact Lenses - K051095

Description of Devices:

Saview SH 38 UV, Saview SH 38 UV toric, Saview SH 38 UV multifocal (Senofilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens:

- The lens designs include spherical, toric and multifocal lenses.

- UV absorbing monomer is used. The transmittance are 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 device is used.
- The lens contains 38% water by weight and each lens is supplied sterile in a blister container in saline solution.

Indication for Use:

Saview SH 38 UV (Senofilcon 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 SH 38 UV toric (Senofilcon 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 SH 38 UV multifocal (Senofilcon 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 SH 38 UV, Saview SH 38 UV toric, and Saview SH 38 UV multifocal (Senofilcon 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).

Comparison of technological characteristics with the predicate device

	Subject Device	Predicate Device	Predicate Device
Device	Saview SH 38 UV, Saview SH 38 UV toric, Saview SH 38 UV multifocal (Senofilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens	VISTAKON (SENOFILCON A) SOFT CONTACT LENS (K042275)	The 55 UV, 55 UV Multifocal, 55 UV Toric (methafilcon A) Soft (Hydrophilic) Daily Wear Contact Lens (K051095)
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 1.00D 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 that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that 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 10.00D 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 2.50 diopters of astigmatism. Cylinder power is 0.50 D to -2.50 D

	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 0.75D of astigmatism or less.	**Multifocal:** Daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia inaphakic or not-aphakic person with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity. Continuous add power to +3.25D
Modality	Daily disposable and frequent replacement wear	Daily disposable and frequent replacement wear	Daily disposable and frequent replacement wear
Material (Classification)	Group 5C (Silicone hydrogel: low water subgroup)	Group 5C (Silicone hydrogel: low water subgroup)	Group 4 methafilcon A
USAN Name	Senofilcon A	Senofilcon A	methafilcon A
Indication for use	Myopia, hyperopia, presbyopia, astigmatism	Myopia, hyperopia, presbyopia, astigmatisn	Myopia, hyperopia, presbyopia, astigmatisn
Water content	38%	38%	55%
Visible light transmittance	≧90%	≧78%	90.3%
UV transmittance	UVB <5% UVA<50%	UVB<1% UVA <10%	UVB: 2.435% UVA: 15.816%
Dk(35°C) non-edge corrected	122 x 10^{-11}	122 x 10^{-11}	18.9 x 10^{-11}
Dk(35°C) boundary layer and edge corrected	103 x 10^{-11}	103 x 10^{-11}	N/A

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)	N/A	+4.00 to -20.00D Cylinder power: 0.50 to -2.50D (for toric only) Continuous add power to +3.25D (for multifocal only)
Color	Tint: [Phthalocyaninato(2-)] copper	Tint: Reactive Blue Dye #4	Tint: Pigment 15
Refractive index	1.42	1.42	1.410
Method of manufacture	Moulded	Moulded	Moulded
Packaging materials	PP (Polypropylene) blister and Aluminum foil	N/A	PP (Polypropylene) blister and Aluminum foil
Package storage saline solution	Saline solution	0.005% methyl ether cellulose	Saline solution

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 ownership of K051095 was transferred from Optical Connection, Inc. to our firm, St. Shine Optical Co., Ltd.. The biocompatibility testing for packaging solution referenced in K051095 is held by our firm as well. Therefore, the material of packaging solution, saline solution, is identical to that of K051095.

For packaging material:
The ownership of K051095 was transferred from Optical Connection, Inc. to our firm, St. Shine Optical Co., Ltd.. The biocompatibility testing for packaging material referenced in K051095 is held by our firm as well. 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, the packaging materials are identical to that of K051095.

The testing performed on Saview SH 38 UV (Senofilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens, Saview SH 38 UV toric (Senofilcon A) Visibility Tinted Soft (Hydrophilic) Contact Lens, Saview SH 38 UV multifocal (Senofilcon 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.

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 Senofilcon A lens material is identical to that of K042275. Safety and effectiveness of packaging material and package storage saline solution is identical to that of K051095.

Substantial Equivalence Conclusion:

The information submitted in the 510(k) establishes that the Saview SH 38 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 SH 38 UV, Saview SH 38 UV toric, Saview SH 38 UV multifocal (Senofilcon A) Soft (Hydrophilic) Contact Lens are substantially equivalent to the predicate devices.