DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 21, 2016

St. Shine Optical Co., Ltd.
Ms. Ella Lee
Project Manager, R&D Div.
4,5F No. 276-2, Sec. 1, Ta Tung Rd., Hsi Chih Dist.
New Taipei City, TW 22146

Re: K162317
Trade/Device Name: Saview-Colors Aqua 42 UV (hefilcon A) Soft (hydrophilic) Contact Lens, Saview-Colors Aqua 42 UV Toric (hefilcon A) Soft (hydrophilic) Contact Lens, Saview-Colors Aqua 42 UV Multifocal (hefilcon A) 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: August 15, 2016
Received: September 2, 2016

Dear Ms. 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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose, and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162317

Device Name
Saview-Colors Aqua 42 UV (hefilcon A) Soft (Hydrophilic) Contact Lens
Saview-Colors Aqua 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lens
Saview-Colors Aqua 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lens

Indications for Use *(Describe)*

The Saview-Colors Aqua 42 UV (hefilcon A) 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 that may exhibit refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity. The Saview-Colors Aqua 42 UV also acts to enhance or alter the apparent color of the eye.

The Saview-Colors Aqua 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive astigmatism up to 2.50 diopters that does not interfere with visual acuity. The Saview-Colors Aqua 42 UV Toric lens also acts to enhance or alter the apparent color of the eye.

The Saview-Colors Aqua 42 UV Multifocal (hefilcon A) 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 that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity and require add power of up to +3.25 diopters. The Saview-Colors Aqua 42 UV lens also acts to enhance or alter the apparent color of the eye.

Saview-Colors Aqua 42 UV, Saview-Colors Aqua 42 UV Toric, and Saview-Colors Aqua 42 UV Multifocal lenses are to be prescribed for single-use daily disposable wear and not intended to be cleaned or disinfected and should be discarded after a single use.

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:

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Registration No.:	9617499
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Date Prepared:	Aug.10, 2016

Device:

Common Name:	Soft (Hydrophilic) Contact Lens
Trade/Proprietary Name:	Saview-Colors Aqua 42 UV (hefilcon A) Soft (Hydrophilic) Contact Lens Saview-Colors Aqua 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lens Saview-Colors Aqua 42 UV Multifocal (hefilcon A) 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:

The predicate devices are Saview-Colors 42 UV, Saview-Colors 42 UV Toric, and Saview-Colors 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lens covered under 510(k) K123484 and Saview-Aqua 55 UV, Saview-Aqua 55 UV Toric, and Saview-Aqua 55 UV Multifocal(methafilcon A) Soft (Hydrophilic) Contact Lens covered under 510(k) K121201.

Description of Devices:

The lens material (hefilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and n-vinyl-2-pyrrolidone (NVP) crosslinked with ethylene glycol dimethacrylate (EGDMA). A UV absorbing compound 2-[3-(2H-Benzotriazol-2y1)-4-hydroxyphenyl] ethyl methacrylate is incorporated into the lens polymer. The lens contains 42% water by weight and each lens is supplied sterile in a blister container containing hyaluronic acid polymer in saline solution. The lenses are printed with an intermittent coating containing a combination of the following approved pigments: iron oxides, titanium dioxide, phthalocyanine green and carbazole violet listed in 21 CFR Part 73 and [phthalocyaninato (2-)] copper list in 21 CFR Part 74. The lens designs include spherical, toric and multifocal lenses.

Indication for Use:

The Saview-Colors Aqua 42 UV (hefilcon A) 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 that may exhibit refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity. The Saview-Colors Aqua 42 UV also acts to enhance or alter the apparent color of the eye.

The Saview-Colors Aqua 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive astigmatism up to 2.50 diopters that does not interfere with visual acuity. The Saview-Colors Aqua 42 UV Toric lens also acts to enhance or alter the apparent color of the eye.

The Saview-Colors Aqua 42 UV Multifocal (hefilcon A) 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 that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity and require add power of up to +3.25 diopters. The Saview-Colors Aqua 42 UV Multifocal lens also acts to enhance or alter the apparent color of the eye.

The Saview-Colors Aqua 42 UV, Saview-Colors Aqua 42 UV Toric and Saview-Colors Aqua 42 UV Multifocal lenses are to be prescribed for single-use daily disposable wear and not intended to be cleaned or disinfected and should be discarded after a single use.

Non-Clinical Testing:

The following tests were conducted as recommended by the Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses, revised May 1994.

- Stability Testing
- Toxicology Testing
  - Cytotoxicity
  - Ocular Irritation
  - Acute Systemic Injection
- Physical/Chemical Testing

Clinical Testing:

Clinical data is not required for this submission.

Description of Safety and Substantial Equivalence:

Information submitted in the 510(k) establishes that the Saview-Colors Aqua 42 UV lenses have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that lens properties do not change before the expiration date. Results of acute systemic injection, ocular irritation and in vitro cytotoxicity tests showed the Saview-Colors Aqua 42 UV lenses are substantially equivalent to the predicate device in safety and biocompatibility. Therefore, the Saview-Colors Aqua 42 UV, Saview-Colors Aqua 42 UV Toric, and Saview-Colors Aqua 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lens are substantially equivalent to the predicate devices.

Table 1 Comparison Chart

Device	**Saview-Colors Aqua 42 UV, Saview-Colors Aqua 42 UV Toric, and Saview-Colors Aqua 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lens**	**Saview-Colors 42 UV, Saview-Colors 42 UV Toric, and Saview-Colors 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lens (K123484)**	**Saview-Aqua 55 UV, Saview-Aqua 55 UV Toric, and Saview-Aqua 55 UV Multifocal Soft (Hydrophilic) Contact Lens (K121201)**
Material (Classification)	hefilcon A (Group 1)	hefilcon A (Group 1)	methafilcon A (Group 4)
Indication for use	myopia, hyperopia, presbyopia and astigmatism	myopia, hyperopia, presbyopia and astigmatism	myopia, hyperopia, presbyopia and astigmatism
Water content	42 %	42 %	55 %
Visible light transmittance	97.06 %	97.06 %	96.78 %
UV Transmittance	UVA : 9.22 % UVB : 0.49 %	UVA : 9.22 % UVB : 0.49 %	12.370 % 1.025 %
Dk (35° C)	10.89×10^{-11}	10.89×10^{-11}	21.4×10^{-11}
Powers	+12.00D to -20.00D;	+12.00D to -20.00D;	+12.00D to -20.00D
Refractive index	1.4347 (wet)	1.4347 (wet)	1.404 (wet)
Method of manufacture	Moulded	Moulded	Moulded
Packaging	PP Blister Pack	PP Blister Pack	PP Blister Pack
Colorants	Iron oxides Titanium dioxide [Phthalocyaninato (2-)] copper Phthalocyanine green Carbazole violet	Iron oxides Titanium dioxide [Phthalocyaninato (2-)] copper Phthalocyanine green Carbazole violet	Copper phthalocyanine (visibility tinted)
Package Storage saline solution	Saline solution containing hyaluronic acid polymer	Saline solution	Saline solution containing hyaluronic acid polymer

Conclusion:

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the Saview-Colors Aqua 42 UV, Saview-Colors Aqua 42 UV Toric, and Saview-Colors Aqua 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lens and to establish substantial equivalence to the predicate devices. Information submitted in the 510(k) also establishes that the Saview-Colors Aqua 42 UV lenses do not raise questions of safety and effectiveness. Therefore, the Saview-Colors Aqua 42 UV, Saview-Colors Aqua 42 UV Toric, and Saview-Colors Aqua 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lens are substantially equivalent to the predicate devices.