MAR 2 9 2013

510(k) Summary

Submitter Information:

Address: St. Shine Optical Co., Ltd.
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Hsi Chih Dist., 221, New Taipei City
Taiwan R.O.C.
Registration No.: 9617499
Contact Person: Ella Lee
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Date Prepared: Mar. 12, 2013

Device:

Common Name:	Soft (Hydrophilic) Contact Lens
Trade/Proprietary Name:	Saview-Colors 42 UV (hefilcon A) Soft (Hydrophilic) Contact Lens Saview-Colors 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lens Saview-Colors 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 S 42 UV Single Vision (hefilcon A) Soft (hydrophilic) Lens, T 42 UV Toric (hefilcon A) Soft (hydrophilic) Lens and M 42 UV Multifocal (hefilcon A) Soft (hydrophilic) Lens covered under 510(k) K040900 and FreshLook®, Freshlook® Toric and FreshLook® Progressive (nelfilcon A) One Day Color Contact Lens covered under 510(k) K050213.

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), and using azobisisobutyronitrile (AIBN) as the initiator. A UV absorbing compound 2-[3-(2H-Benzotriazol-2yl)-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 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 Saview-Colors 42 UV (hefilcon A) Soft (Hydrophilic) Contact Lens is available as a single vision lens.

The Saview-Colors 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lens is available in a double slab-off back surface design. The lens design incorporates a cylinder and base curve. From the bi-curve reduced optic front surface, there exists a slab-off of the upper and lower half of the lens. This makes both sides thicker at the horizontal level on the front surface to keep the axis stable.

The Saview-Colors 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lens is available as an aspherical multifocal lens.

Indication for Use:

The Saview-Colors 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 42 UV also acts to enhance or alter the apparent color of the eye.

The Saview-Colors 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 42 UV Toric lens also acts to enhance or alter the apparent color of the eye.

The Saview-Colors 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 42 UV lens also acts to enhance or alter the apparent color of the eye.

Eye care practitioners may prescribe the lenses for single use disposable wear or frequent replacement. When prescribed for a Disposable Wearing Schedule, the lenses are not intended to be cleaned or disinfected and should be discarded after a single use. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems.

The Saview-Colors 42 UV, Saview-Colors 42 UV Toric, and Saview-Colors 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

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 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 Results of acute systemic injection, ocular irritation and in vitro cytotoxicity tests showed the Saview-Colors 42 UV lenses are substantially equivalent to the predicate device in safety and biocompatibility. Therefore, the Saview-Colors 42 UV, Saview-Colors 42 UV Toric, and Saview-Colors 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lens are substantially equivalent to the predicate devices.

Table 1 Comparison Chart

Device	Saview-Colors 42 UV, Saview-Colors 42 UV Toric, and Saview-Colors 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lens	S 42 UV Single Vision, T 42 UV Toric and M 42 UV Multifocal (hefilcon A) Soft (hydrophilic) Lens - K040900	FreshLook® (nelfilcon A) One Day Color Contact Lens - K050213
Material (Classification)	hefilcon A (Group 1)	hefilcon A (Group 1)	nelfilcon A (Group 2)
Indication for use	myopia, hyperopia, presbyopia and astigmatism	myopia, hyperopia, presbyopia and astigmatism	myopia, hyperopia, presbyopia and astigmatism
Water content	42 %	42 %	69 %
Visible light transmittance	97.06 %	90.3 %	Clear≧97 % Vistint 96 %
UV Transmittance	UVA : 0.49 % UVB : 9.22 %	<10 %	N/A
Dk (35° C)	10.89×10^{-11}	13.375×10^{-11}	26×10^{-11}
Powers	+12.00D to -20.00D;	+20.00D to -20.00D;	+20.00D to -20.00D
Refractive index	1.4347 (wet)	1.416 (wet)	1.38 (wet)
Method of manufacture	Moulded	Moulded	Moulded
Packaging	PP Blister Pack	PP Blister Pack	Blister Pack
Package Storage saline solution	Saline solution	Saline solution	Phosphate-acetate buffered saline
Colorants	Iron oxides Titanium dioxide [Phthalocyaninato (2-)] copper Phthalocyanine green Carbazole violet	N/A	Iron oxides Titanium dioxide [Phthalocyaninato (2-)] copper Chromium oxide Carbazole violet

Conclusion:

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the Saview-Colors 42 UV, Saview-Colors 42 UV Toric, and Saview-Colors 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 42 UV lenses do not raise questions of safety and effectiveness. Therefore, the Saview-Colors 42 UV, Saview-Colors 42 UV Toric, and Saview-Colors 42 UV Multifocal (hefilcon A) Soft (Hydrophilic) Contact Lens are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 29, 2013

St. Shine Optical Co., Ltd.
Ms. Ella Lee
Product Manager, R&D Division
4,5 F/L No. 276-2, Sec. 1, Ta Tung Rd.
Hsi Chih Dist., 221, New Taipei City
Taiwan R.O.C.

Re: K123484
Trade/Device Name: Saview-Colors 42 UV (hefilcon A) Soft (Hydrophilic) Contact Lens, Saview-Colors 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lens and Saview-Colors 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: March 5, 2013
Received: March 7, 2013

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Kesia Y. Alexander -S

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

Indications for Use Statement

510(k) Number (if known): K123484

Device Name:

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

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Prescription Use __X__	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marc Robboy
2013.03.21 08:33:09 -04'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number **K123484**