



April 19, 2018

Visco Vision, Inc.
Jennifer Ting
RA Manager
Jens Medical Consulting Ltd.
6F, No. 39, Jixian Rd., Luzhou Dist.
New Taipei City, TW 247

Re: K180322

Trade/Device Name: Si-Hy (olifilcon B) color silicone hydrogel soft contact lens

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (Hydrophilic) Contact Lens

Regulatory Class: Class II

Product Code: LPL, MVN

Dated: January 20, 2018

Received: February 21, 2018

Dear Jennifer Ting:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Denise L. Hampton -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

510(k) Number (if known)
K180322

Device Name
Si-Hy (olofilcon B) Color Silicone Hydrogel Soft (hydrophilic) Contact Lens

Indications for Use (Describe)

The Si-Hy (olofilcon B) Color Spherical Silicone Hydrogel soft contact lenses are daily wear single use soft contact lens indicated for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who exhibit refractive astigmatism of 1.00D or less where the astigmatism does not interfere with visual acuity.

The Si-Hy (olofilcon B) Color Toric Silicone Hydrogel Soft Contact Lenses are indicated as daily wear for the correction of ametropia (myopia and hyperopia) with astigmatism in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -20.00 to +20.00 diopters and astigmatic corrections are from -0.75 to -2.25 diopters.

The Si-Hy (olofilcon B) Color Multifocal Silicone Hydrogel Soft Contact lenses are indicated as daily wear for the correction of ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -20.00 to +20.00 diopters with add powers from +0.75 to +2.75 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopters or less where the astigmatism does not interfere with visual acuity.

The lens may also be indicated to enhance or alter the apparent color of the eye. Eye care practitioners may prescribe the lens for daily wear (disposable use) single use. The lenses are to be discarded upon removal. Therefore, no cleaning or disinfecting is required.

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

Preparation Date: April 11, 2018

1.1 Establishment Information:

Name Visco Vision Inc.
Address No. 1, Xingye St., Guishan Dist., Taoyuan City 33341 Taiwan
Contact Ted TT Huang
Phone No. 886-3-3596868
Fax No. 886-3-3490202

1.2 Contact Person:

Name Evan Huang
Phone No. 886-3-3596868
Fax No. 886-3-3490202
e-mail: evan.huang@viscovision.com.tw

1.3 Device Identification:

Proprietary Name Si-Hy (olifilcon B) Color Silicone Hydrogel Soft Contact Lens
Common Name Soft (hydrophilic) Contact Lenses
Classification Name Soft (hydrophilic) contact lens. (21 CFR 886.5925)
Product Codes LPL, MVN
Classification II

1.4 Legally Marketed Equivalent Device:

Intended use

Predicate Device Name Saview-Color Aqua 42 UV (hefilcon A) soft (hydrophilic) contact lens
Manufacturer St. Shine Optical Co., Ltd.
510(k) Number K162317
Product Codes LPL, MVN

Lens material

Predicate Device Name Si-Hy (olifilcon B) silicone hydrogel soft contact lens
Manufacturer Visco Vision Inc.
510(k) Number K160344
Product Codes LPL, MVN

1.5 Device Description

The Si-Hy (olifilcon B) Color Silicone Hydrogel Soft (Hydrophilic) Contact Lenses

are available as spherical lens, toric lens and multifocal lens with cosmetic tint in an annular pattern by providing a clear optic zone. They are marked in different color by containing a combination of the following color additives: Iron oxide, [Phthalocyaninato (2-)] copper, Titanium dioxide, Phthalocyanine green, Carbazole violet. The lens material is composed by 53% olifilcon B and 47% water. A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are 2.2% (<5%) in the UVB range of 280-315nm and 8.7% (<50%) in the UVA range of 316-380nm. All colored additives used including ultraviolet absorbing additive (benzophenone based) are listed in 21CFR 73 subpart D and 74 subpart D.

1.6 Indication for Use:

The Si-Hy (olifilcon B) **Color Spherical** Silicone Hydrogel soft contact lenses are daily wear single use soft contact lens indicated for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who exhibit refractive astigmatism of 1.00D or less where the astigmatism does not interfere with visual acuity.

The Si-Hy (olifilcon B) **Color Toric** Silicone Hydrogel Soft Contact Lenses are indicated as daily wear for the correction of ametropia (myopia and hyperopia) with astigmatism in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -20.00 to +20.00 diopters and astigmatic corrections are from -0.75 to -2.25 diopters.

The Si-Hy (olifilcon B) **Color Multifocal** Silicone Hydrogel Soft Contact lenses are indicated as daily wear for the correction of ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes and whose powers are from -20.00 to +20.00 diopters with add powers from +0.75 to +2.75 diopters. The lenses may be worn by persons who exhibit astigmatism of 1.00 diopters or less where the astigmatism does not interfere with visual acuity.

The lens may also be indicated to enhance or alter the apparent color of the eye. Eye care practitioners may prescribe the lens for daily wear (disposable use) single use. The lenses are to be discarded upon removal. Therefore, no cleaning or disinfecting is required.

1.7 Technological characteristic

Si-Hy Color SPHERICAL Soft Contact Lenses characteristics:

- Diameter Range : 13.00 to 15.00 mm
- Base Curve : 8.00 to 9.20 mm
- Center Thickness : 0.08 mm for -3.00D (varies with power)
- Power : +20.00 to -20.00 D

Si-Hy Color TORIC Soft Contact Lenses characteristics:

- Diameter Range : 13.00 to 15.00 mm
- Base Curve : 8.00 to 9.20 mm
- Center Thickness : 0.08 mm for -3.00D (varies with power)
- Power : +20.00 to -20.00 D
- Cylinder: -0.75D ~ -2.25D
- Axis: 10° to 180° (in 10° increments)

Si-Hy Color MULTIFOCAL Soft Contact Lenses characteristics:

- Diameter Range : 13.00 to 15.00 mm
- Base Curve : 8.00 to 9.20 mm
- Center Thickness : 0.08 mm for -3.00D (varies with power)
- Power : +20.00 to -20.00 D
- Additional Powers: +0.75D ~ +1.25D (LOW)
+1.50D ~ +2.00D (MID)
+2.25D ~ +2.75D (HIGH)

1.8 Comparison table:

The characteristic comparison to predicate device is summarized in the following table.

Similarities and differences			
Item	Device	Predicate (K160344)	Predicate (K162317)
Product Name	Si-Hy (olifilcon B) Color Silicone Hydrogel soft contact lens	Si-Hy (olifilcon B) Silicone Hydrogel soft contact lens	Saview-Color Aqua 42 UV (hefilcon A) soft (hydrophilic) contact lens
Manufacturer	Visco Vision Inc.	Visco Vision Inc.	St. Shine Optical Co., ltd
Intended Use	Myopia, Hyperopia, astigmatism, Presbyopia	The same	The same

Lens Design	Spherical, toric, or multifocal	The same	The same
Replacement Schedule	Daily Disposable (Single use)	The same	The same
Chemical composition	olifilcon B	olifilcon B	Hefilcon A
Classification	Group 5C (Nonionic, Water < 50 wt %)	The same	The same
Water Content	47 % (<50%),	The same	42%
Oxygen Permeability (DK, 35°C)	120 (Fatt method)	The same	10.89
Base Curve Range (mm)	8.0~9.2	The same	NA
Diameter (mm)	13.0~15.0	The same	NA
Center Thickness	Varies with design and power (0.08 mm at -3.00D)	The same	NA
Powers	-20.00D to +20.00D	The same	-20.00D -+12.00D
Refractive Index	1.410	The same	1.435
Light Transmittance	94%	The same	97%
Visibility Tint	NA	Reactive Blue19	NA
Color additives for print	Iron oxide, [Phthalocyaninato (2-)] copper Titanium dioxide, Phthalocyanine green, Carbazole violet	NA	iron oxide Titanium dioxide [Phthalocyaninato (2-)] copper Phythalocyanine green Carbazole violet
Method of Manufacture	Molded	Molded	Moulded

1.9 Nonclinical Tests Performed

1.9.1 Physiochemical studies were conducted according to ISO 18369, Ophthalmic optics - Contact lenses (Ophthalmic). The physical, optical and chemical properties of the lens are within established specifications for the lenses.

1.9.2 Toxicology studies report shows that the lenses are non-toxic and biocompatibility result is acceptable in ocular environment.

1.10 Clinical Studies

The lens material is the same as the Si-Hy (olifilcon B) silicone hydrogel soft (hydrophilic) contact lens currently available (K141348). The color additives used is the same as Saview-Color Aqua 42 UV (hefilcon A) soft (hydrophilic) contact

lens currently available (K162317). Therefore, the clinical data is not required.

1.11 Conclusion

Comparison to the predicate device for chemical composition, physical and optical properties, it shows that “Si-Hy (olicofilcon B) color silicone hydrogel soft (hydrophilic) contact lens” is as safe, as effective and performs as well as the predicate device.