



October 2, 2019

Visco Vision Inc.
% Ms. Jennifer Ting
Manager
Jens Medical Consulting Ltd.
3F, No. 364, Jixian Rd., Luzhou Dist.
247 New Taipei City, Taiwan R.O.C.

Re: K191397

Trade/Device Name: OxySoft (olifilcon C) 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: August 26, 2019
Received: August 27, 2019

Dear Ms. 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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 <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, 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

510(k) Number (if known)

K191397

Device Name

OxySoft (olofilcon C) Silicone Hydrogel Soft Contact Lens

Indications for Use (Describe)

The OxySoft (olofilcon C) 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 OxySoft (olofilcon C) 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 OxySoft (olofilcon C) 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.

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: July 16, 2019

5.1 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

5.2 Contact Person:

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

5.3 Device Identification:

Proprietary Name OxySoft (olifilcon C) Silicone Hydrogel Soft Contact Lens
Common Name Soft (hydrophilic) Contact Lenses
Classification Name Lenses, Soft Contact, Daily Wear,
(21 CFR 886.5925, Product Code LPL)
Lenses, Soft Contact, Daily Wear (Disposable),
(21 CFR 886.5925, Product Code MVN)
Classification II

5.4 Legally Marketed Equivalent Device:

Predicate Device Name Si-Hy (olifilcon B) Silicone Hydrogel Soft Contact Lens
Manufacturer Visco Vision Inc.
510(k) Number K160344
Product Code MVN

5.5 Device Description

The OxySoft (olofilcon C) Silicone Hydrogel Soft Contact Lens is made of silicone hydrogel material with UV blocker available as spherical lens, toric lens and multifocal lens. The composition of the lens is 46% olifilcon C and 54 % water. A light blue color tinted with “reactive Blue19” is for handling visibility purpose. A benzotriazole UV absorbing monomer is used to block UV radiation. The transmittance characteristics are 1.9% ($<5\%$) in the UVB range of 280-315nm and 14.7% ($<50\%$) in the UVA range of 316-380nm. It is supplied in a sterile state packaged in a buffered saline solution.

5.6 Indication for Use:

The OxySoft (olofilcon C) **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 OxySoft (olofilcon C) **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 OxySoft (olofilcon C) **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.

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.

5.7 Technological characteristic

OxySoft SPHERICAL Soft Contact Lenses characteristics:

- Diameter Range : 13.0 to 15.0 mm
- Base Curve : 8.0 to 9.2 mm
- Center Thickness : 0.08 mm for -3.00D (varies with power)
- Power : +20.00 to -20.00 D

OxySoft TORIC Soft Contact Lenses characteristics:

- Diameter Range : 13.0 to 15.0 mm
- Base Curve : 8.0 to 9.2 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)

OxySoft MULTIFOCAL Soft Contact Lenses characteristics:

- Diameter Range : 13.0 to 15.0 mm
- Base Curve : 8.0 to 9.2 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)

5.8 Comparison table:

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

Similarities and differences		
Item	Device	Predicate (K160344)
Product Name	OxySoft (olofilcon C) Silicone Hydrogel soft contact lens	Si-Hy (olofilcon B) Silicone Hydrogel soft contact lens
Manufacturer	VISCO VISION Inc.	VISCO VISION Inc.
Intended Use	Myopia, Hyperopia, astigmatism, Presbyopia	The same
Lens Design	Spherical, toric, or multifocal	The same
Replacement Schedule	Daily Disposable (Single use)	The same
Chemical composition	olofilcon C	olofilcon B

Classification	Group II (Nonionic, High water)	Group I (Nonionic, Low water)
Water Content	54 %	47 % (<50%),
Oxygen Permeability (DK, 35°C)	100 (Fatt method)	120 (Fatt method)
Base Curve Range (mm)	8.0~9.2	8.0~9.2
Diameter (mm)	13.0~15.0	13.0~15.0
Center Thickness	Varies with design and power (0.08 mm at -3.00D)	Varies with design and power (0.08 mm at -3.00D)
Powers	-20.00D to +20.00D	-20.00D to +20.00D
Refractive Index	1.396	1.410
Light Transmittance	94%	94%
Blue handling tint	Reactive Blue19	Reactive Blue19
Method of Manufacture	Molded	Molded

5.9 Nonclinical Tests Performed

- 5.9.1** Physiochemical studies were conducted according to ISO 18369 First edition 2006-08-15, Ophthalmic optics - Contact lenses (Ophthalmic). The physical, optical and chemical properties of the lens are within established specifications for the lenses.
- 5.9.2** Toxicology studies report shows that the lenses are non-toxic and biocompatibility result is acceptable in ocular environment.

5.10 Clinical Studies

A one-month clinical study was conducted to demonstrate the safety and effectiveness of the OxySoft (olifilcon C) silicone hydrogel soft contact lens by comparison with Si-Hy (olifilcon B) silicone hydrogel soft contact lens when worn on a daily wear basis. At least 30 evaluable subjects were participated. Parameters measured include visual acuities, slit lamp findings, symptom, problem and complaints, adverse reactions, as well as lens wearing time.

The study evaluated thirty six (36) male and female subjects who were randomized and dispensed lenses in a 2:1 ratio with 24 subjects dispensed into the Trial lenses and 12 Subjects dispensed into the Control lenses. Of the 36 subjects who were enrolled in the study, 35 subjects were female and 1 subject was male. All of them are Asia people. The subject ranged in age from 22 years to 59 years. The gender ratio is 1 male to 35 females. One subject is new contact lens wearer (2.78%) and 35 subjects (97.22%) have successful experience with daily wear soft contact lens.

In trial group, 24 subjects range in age from 22 years to 59 years with average 33.29 ± 10.02 years. All of the subjects are female. The gender ratio is 24 to 0 (24 female/0 male). In control group, 12 subjects range in age from 25 years to 46 years with average 35.58 ± 7.09 years. One subject is male and 11 subjects female. The gender ratio was 11 to 1 (11 female/1 male).

It was found that the OxySoft silicone hydrogel soft contact lens is safe as a daily disposable single use lens to wear up to 9 hours a day during 30 days follow up by comparing to Si-Hy (olofilcon B) silicone hydrogel soft contact lens. There is no symptom or syndrome that requires treatment for all subjects during study period.

The mean visual acuity (VA) for both lenses was similar at each visit. The visual acuity could be corrected to 0.1 LogMAR or better. None of the subjects had VA decreased more than 2 lines. No significant slit lamp findings (i.e. Grade 3 or Grade 4) were found. No adverse event (AE) occurred.

5.11 Conclusion

Comparison to the predicate device for chemical composition, physical and optical properties, it shows that “OxySoft silicone hydrogel soft contact lens” is as safe, as effective and performs as well as the predicate device.