April 3, 2018

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

Re: K173958
Trade/Device Name: OxyAqua (olifilcon D) spherical silicone hydrogel soft contact lens,
OxyAqua (olifilcon D) multifocal silicone hydrogel soft contact lens,
OxyAqua (olifilcon D) toric 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: December 24, 2017
Received: February 5, 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 yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173958

Device Name
OxyAqua (olifilcon D) Silicone Hydrogel Soft (hydrophilic) Contact Lens

Indications for Use *(Describe)*
The OxyAqua (olifilcon D) Spherical Silicone Hydrogel soft (hydrophilic) 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 OxyAqua (olifilcon D) Toric Silicone Hydrogel Soft (hydrophilic) 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 OxyAqua (olifilcon D) Multifocal Silicone Hydrogel Soft (hydrophilic) 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 K173958

Preparation Date: March 20, 2018

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.	886-3-3490202
Fax No.	886-3-3596868

5.2 Contact Person:

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

5.3 Device Identification:

Proprietary Name	OxyAqua (olifilcon D) 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 OxyAqua (olifilcon D) 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 42% olifilcon D and 58 % 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 2.4% (＜5%) in the UVB range of 280-315nm and 13.7% (＜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 OxyAqua (olifilcon D) **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 OxyAqua (olifilcon D) **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 OxyAqua (olifilcon D) **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

OxyAqua 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

OxyAqua 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: 10º to 180º (in 10º increments)

OxyAqua 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	OxyAqua (olifilcon D) Silicone Hydrogel soft contact lens	Si-Hy (olifilcon B) Silicone Hydrogel soft contact lens
Manufacturer	VISCO VISION Inc.	VISCO VISION Inc.
Intended Use	Myopia, Hyperopia	Myopia, Hyperopia, astigmatism, Presbyopia
Lens Design	Spherical, toric, or multifocal	Spherical, toric, or multifocal
Replacement Schedule	Daily Disposable (Single use)	Daily Disposable (Single use)
Chemical composition	Olifilcon D	Olifilcon B
Classification	Group II (High water, nonionic)	Group I (Nonionic, Low water)
Water Content	58 %	47 % (<50%),
Oxygen Permeability (DK, 35℃)	85 (Fatt method)	120 (Fatt method)

Base Curve Range (mm)	8.2~9.0	8.0~9.2
Diameter (mm)	13.8~14.4	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 in 0.25 steps	-20.00D to +20.00D
Refractive Index	1.394	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 three-month clinical study was conducted to demonstrate the safety and effectiveness of the OxyAqua (olifilcon D) 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, adverse reactions, symptom, problem and complaints, slit lamp findings, as well as lens wearing time. It was found that the mean VA for both lenses was similar at each visit. The visual acuity could be corrected to 0.1 (log MAR) or better. No significant slit lamp findings (i.e. Grade 3 or Grade 4) were noted. No significant differences in slit-lamp findings were found between groups.

The clinical study provided data to establish substantial equivalence with the predicate, control lens, Si-Hy (olifilcon B) silicone hydrogel soft contact lens, Visco Vision Inc. (K160344), with respect to the safety and effectiveness.

5.11 Conclusion

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