October 23, 2026

Visco Vision, Inc.
Janice Yu
Regulatory Affairs
1, Xingye St., Guishan Dist.,
Taoyuan City, 33341
Taiwan

Re: K253875
Trade/Device Name: OxyPure (olifilcon A) Spherical Biweekly Silicone Hydrogel Soft Contact Lens
OxyPure (olifilcon A) Toric Biweekly Silicone Hydrogel Soft Contact Lens
OxyPure (olifilcon A) Multifocal Biweekly 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 28, 2026
Received: September 14, 2026

Dear Janice Yu:

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 (the 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 available 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253875

Please provide the device trade name(s).

OxyPure (olifilcon A) Spherical Biweekly Silicone Hydrogel Soft Contact Lens;
OxyPure (olifilcon A) Toric Biweekly Silicone Hydrogel Soft Contact Lens;
OxyPure (olifilcon A) Multifocal Biweekly Silicone Hydrogel Soft Contact Lens

Please provide your Indications for Use below.

OxyPure (olifilcon A) Spherical Biweekly Silicone Hydrogel Soft Contact Lens is indicated as daily wear and bi-weekly disposable soft contact lens 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.

OxyPure (olifilcon A) Toric Biweekly Silicone Hydrogel Soft Contact Lens is indicated as daily wear and bi-weekly disposable soft contact lens 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 -12.00 to +8.00 diopters and astigmatic corrections are from -0.75 to -2.25 diopters.

OxyPure (olifilcon A) Multifocal Biweekly Silicone Hydrogel Soft Contact Lens is indicated as daily wear and bi-weekly disposable soft contact lens 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 -12.00 to +8.00 diopters with add powers from +0.25 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K253875

510(k) Summary

- **Type of Submission:** Traditional
- **Date of Summary:** 12/03/2025
- **Submitter:** Visco Vision Inc.
  - Address: No. 1, Xingye St., Guishan Dist., Taoyuan City, 33341, Taiwan (R.O.C.)
  - Phone: +886-3-3596868
  - Contact: Janice Yu (janice.hy.yu@viscovision.com.tw)
- **Identification of the Device:**
  - Proprietary/Trade name: OxyPure (olifilcon A) Spherical Biweekly Silicone Hydrogel Soft Contact Lens; OxyPure (olifilcon A) Toric Biweekly Silicone Hydrogel Soft Contact Lens; OxyPure (olifilcon A) Multifocal Biweekly Silicone Hydrogel Soft Contact Lens
  - Classification Product Code: LPL, MVN
  - Regulation Number: 886.5925
  - Regulation Description: Soft (hydrophilic) contact lens
  - Review Panel: Ophthalmic
  - Device Class: II
- **Identification of the Predicate Device I:**
  - Predicate Device Name: Visco Soft Contact Lens
  - Manufacturer: Visco Technology Sdn. Bhd.
  - Classification Product Code: LPL, MVN
  - Regulation number: 886.5925
  - Device Class: II
  - 510(k) Number: K141348
- **Identification of the Predicate Device II:**
  - Predicate Device Name: VISCO (olifilcon A) Soft Contact Lens
  - Manufacturer: Visco Technology Sdn. Bhd.
  - Classification Product Code: LPL, MVN
  - Regulation number: 886.5925
  - Device Class: II
  - 510(k) Number: K160245

- **Indications for Use of the Device**

  OxyPure (olifilcon A) Spherical Biweekly Silicone Hydrogel Soft Contact Lens is indicated as daily wear and bi-weekly disposable soft contact lens 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.

  OxyPure (olifilcon A) Toric Biweekly Silicone Hydrogel Soft Contact Lens is indicated as daily wear and bi-weekly disposable soft contact lens 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 -12.00 to +8.00 diopters and astigmatic corrections are from -0.75 to -2.25 diopters.

  OxyPure (olifilcon A) Multifocal Biweekly Silicone Hydrogel Soft Contact Lens is indicated as daily wear and bi-weekly disposable soft contact lens 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 -12.00 to +8.00 diopters with add powers from +0.25 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.

- **Device Description**

  The OxyPure (olifilcon A) Spherical Biweekly Silicone Hydrogel Soft Contact Lens, OxyPure (olifilcon A) Toric Biweekly Silicone Hydrogel Soft Contact Lens and OxyPure (olifilcon A) Multifocal Biweekly Silicone Hydrogel Soft Contact Lens are made of hydrogel material, olifilcon A, with UV blocker available as spherical lens, toric lens and multifocal lens. The composition of the contact lens is 53% olifilcon A, which is a copolymer of 1-vinyl-2-pyrrolidinone (NVP) and Siloxane macromer, and 47% water. A light blue color tinted with “reactive Blue19” listed in 21 CFR Part 73.3121is for handling visibility purpose. A benzotriazole UV absorbing monomer is used to block UV radiation. The UV transmission (the thinnest lens measured by spectrophotometry as stated in ISO 18369) is less than 50% in the UVA range of 315 - 380 nm and less than 5% in the range of UVB range of 280-315 nm.

  Lenses are supplied sterile in sealed blister packs containing isotonic buffered saline solution. The compatibility and package integrity of the blister pack packaging system has been demonstrated and successfully used for other marketed lens products, and packaged lenses are effectively steam sterilized in a validated autoclave. Blister pack

containers are labeled with the lens parameters, lot number and product expiration date. The expiration date has been established through stability studies that have assessed the chemical stability of the lens and package integrity (ability to maintain sterility). Shelf-life studies are ongoing to establish and extend the labeled expiration date.

- **Non-clinical Testing**
  The following non-clinical performance testing was submitted to support the determination of substantial equivalence between the subject device and the predicate device:

  — **Sterilization Test**
  — **Shelf life test**
    - Visual Inspection Test
    - Bubble Emission Test
    - Dye Penetration Test
    - Seal Strength Test
    - Transportation Test

  — **Biocompatibility test**
    Soft Contact Lens:
    - Cytotoxicity Test (ISO 10993-5)
    - Ocular Irritation Test (ISO 10993-10 / ISO 10993-23)
    - Acute Systemic Toxicity Study (ISO 10993-11)

    Primary packaging solution:
    - In accordance with FDA's ISO 10993-1 guidance, additional biocompatibility testing for the primary packaging is exempt based on the Attachment F declaration confirming identical packaging materials to the predicate devices (K141348 and K160245).

    Packaging Materials:
    - Cytotoxicity Test (ISO 10993-5)
    - Ocular Irritation Test (ISO 10993-10 / ISO 10993-23)
    - Acute Systemic Toxicity Study (ISO 10993-11)

  — **Performance Test**
    - Power (Back Vertex Power, Addition power, Cylinder power)

- Radius of Curvature
- Lens Diameter
- Thickness
- Inspection of Surface
- Spectral & UV Transmittance
- Refractive Index
- PH & Osmolality of Packaging Solution
- Tensile Strength
- Modulus
- Elongation at Break
- Toughness
- Water Content
- Product Chemical Extraction
- Physical Compatibility
- Preservative Aldox & PAPB
- Specific Gravity
- Oxygen Permeability.

All the test results demonstrate the subject device meets the requirements of its pre-defined acceptance criteria and intended use and is substantially equivalent to the predicate device.

- **Clinical Testing**
  No clinical test data was used to support the decision of substantial equivalence.

- **Substantial Equivalence Determination**
  Please refer to the following comparison table:

Item	Subject device	Predicate device (K160245)
Product Name	OxyPure (olifilcon A) Toric Biweekly Silicone Hydrogel Soft Contact Lens	VISCO (olifilcon A) Toric Soft Contact Lens
Manufacturer	Visco Technology Sdn. Bhd.	Visco Technology Sdn. Bhd.
Product code	LPL, MVN	LPL, MVN
Classification	Class II (21 CFR 886.5925)	Class II (21 CFR 886.5925)
Intended Use	Myopia, Hyperopia, Astigmatism	Myopia, Hyperopia, Astigmatism
Indication for Use	OxyPure (olifilcon A) Toric	The VISCO (olifilcon A) Toric

	Biweekly Silicone Hydrogel Soft Contact Lens is indicated as daily wear daily wear and bi-weekly disposable soft contact lens 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 -12.00 to +8.00 diopters and astigmatic corrections are from -0.75 to -2.25 diopters.	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. Eye care practitioners may prescribe the lens for either single-use daily disposable wear, or for frequent/planned replacement wear, with cleaning, disinfection, and scheduled replacement. When prescribed for frequent replacement, the lens may be disinfected using a chemical disinfection system only.
Replacement Schedule	Daily wear (Biweekly)	Daily wear (monthly)
USAN Name	olifilcon A	olifilcon A
Material	Silicone Hydrogel	Silicone Hydrogel
Packaging materials	PP blister and Aluminum foil	PP blister and Aluminum foil
Packaging storage saline solution	Saline solution	Saline solution
Lens Design	Toric	Toric
Type	Group I (low water, nonionic)	Group I (low water, nonionic)
Water Content	47 %	47 %
Oxygen Permeability (DK, 35℃)	150 (Fatt method)	150 (Fatt method)
Base Curve Range	8.40 ~ 9.20	8.0 ~ 9.2
Diameter (mm)	13.80 ~ 14.60	13.0 ~ 15.0

Center Thickness	Varies with power (0.08 mm at -3.00D)	Varies with power (0.08 mm at -3.00D)
Powers	+8.00D to -12.00D	-20.00D to +20.00D in 0.25 steps
Cylinder Power (Toric)	-0.75D, -1.25D, -1.75D, -2.25D Axis from 10º to 180º (in 10º increments)	-0.75D, -1.25D, -1.75D, -2.25D Axis from 10º to 180º (in 10º increments)
Refractive Index	1.410	1.410
Light Transmittance	94%	94%
Method of Manufacture	Cast-Molded	Cast-Molded
Surface Treatment	No	No
Sterilization	Steam	Steam
Packaging	Blister pack	Blister pack
Blue handling tint	Yes, reactive Blue19	Yes, reactive Blue19
Cleaning and Disinfection	Chemical disinfection system only	Chemical disinfection system only

Item	Subject device	Predicate device (K160245)
Product Name	OxyPure (olifilcon A) Multifocal Biweekly Silicone Hydrogel Soft Contact Lens	VISCO (olifilcon A) Multifocal Soft Contact lenses
Manufacturer	Visco Technology Sdn. Bhd.	Visco Technology Sdn. Bhd.
Product code	LPL, MVN	LPL, MVN
Classification	Class II (21 CFR 886.5925)	Class II (21 CFR 886.5925)
Intended Use	Myopia, Hyperopia, Presbyopia	Myopia, Hyperopia, Presbyopia
Indication for Use	OxyPure (olifilcon A) Multifocal Biweekly Silicone Hydrogel Soft Contact Lens is indicated as daily wear and bi-weekly disposable soft contact lens for the correction of ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic	The VISCO (olifilcon A) Multifocal 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

	and non-aphakic persons with non-diseased eyes and whose powers are from -12.00 to +8.00 diopters with add powers from +0.25 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.	+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 either single-use daily disposable wear, or for frequent/planned replacement wear, with cleaning, disinfection, and scheduled replacement. When prescribed for frequent replacement, the lens may be disinfected using a chemical disinfection system only.
Replacement Schedule	Daily wear (Biweekly)	Daily wear (monthly)
USAN Name	olifilcon A	olifilcon A
Material	Silicone Hydrogel	Silicone Hydrogel
Packaging materials	PP blister and Aluminum foil	PP blister and Aluminum foil
Packaging storage saline solution	Saline solution	Saline solution
Lens Design	Multifocal	Multifocal
Type	Group I (low water, nonionic)	Group I (low water, nonionic)
Water Content	47 %	47 %
Oxygen Permeability (DK, 35℃)	150 (Fatt method)	150 (Fatt method)
Base Curve Range	8.40 ~ 9.20	8.0 ~ 9.2
Diameter (mm)	13.80 ~ 14.60	13.0 ~ 15.0
Center Thickness	Varies with power (0.08 mm at -3.00D)	Varies with power (0.08 mm at -3.00D)
Powers	+8.00D to -12.00D	-20.00D to +20.00D in 0.25 steps
Additional Powers	Low (up to +1.25D)	Low (+0.75D ~ +1.25D)

	Mid (up to +2.00D) High (up to +2.75D)	Mid (+1.50D ~ +2.00D) High (+2.25D ~ +2.75D)
Refractive Index	1.410	1.410
Light Transmittance	94%	94%
Method of Manufacture	Cast-Molded	Cast-Molded
Surface Treatment	No	No
Sterilization	Steam	Steam
Packaging	Blister pack	Blister pack
Blue handling tint	Yes, reactive Blue19	Yes, reactive Blue19
Cleaning and Disinfection	Chemical disinfection system only	Chemical disinfection system only

Item	Subject device	Predicate device (K141348)
Product Name	OxyPure (olifilcon A) Spherical Biweekly Silicone Hydrogel Soft Contact Lens	VISCO Soft (Hydrophilic) Contact Lenses
Manufacturer	Visco Technology Sdn. Bhd.	Visco Technology Sdn. Bhd.
Product code	LPL, MVN	LPL, MVN
Classification	Class II (21 CFR 886.5925)	Class II (21 CFR 886.5925)
Intended Use	Myopia, Hyperopia	Myopia, Hyperopia
Indication for Use	OxyPure (olifilcon A) Spherical Biweekly Silicone Hydrogel Soft Contact Lens is indicated as daily wear and bi-weekly disposable soft contact lens 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 VISCO Soft (Hydrophilic) Contact Lenses is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who exhibit refractive astigmatism of 2.00D or less where the astigmatism does not interfere with visual acuity. Eyecare practitioners may prescribe the lens for either single-use disposable wear, or for frequent/planned replacement wear, with cleaning, disinfection, and scheduled replacement.

		When prescribed for frequent replacement, the lens may be disinfected using a chemical disinfection system only. The VISCO Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.
Replacement Schedule	Daily wear (Biweekly)	Daily wear (monthly) or Daily Disposable (Single use)
USAN Name	olifilcon A	olifilcon A
Material	Silicone Hydrogel	Silicone Hydrogel
Packaging materials	PP blister and Aluminum foil	PP blister and Aluminum foil
Packaging storage saline solution	Saline solution	Saline solution
Lens Design	Spherical	Spherical
Type	Group I (low water, nonionic)	Group I (low water, nonionic)
Water Content	47 %	47 %
Oxygen Permeability (DK, 35℃)	150 (Fatt method)	150 (Fatt method)
Base Curve Range	8.40 ~ 9.20	8.0 ~ 9.2
Diameter (mm)	13.80 ~ 14.50	13.0 ~ 15.0
Center Thickness	Varies with power (0.08 mm at -3.00D)	Varies with power (0.08 mm at -3.00D)
Powers	+8.00D to -12.00D	-20.00D to +20.00D in 0.25 steps
Refractive Astigmatism	1.00D or less	2.00D or less
Refractive Index	1.410	1.410
Light Transmittance	94%	94%
Method of Manufacture	Cast-Molded	Cast-Molded
Surface Treatment	No	No
Sterilization	Steam	Steam
Packaging	Blister pack	Blister pack
Blue handling tint	Yes, reactive Blue19	Yes, reactive Blue19

Cleaning and Disinfection	Chemical disinfection system only	Chemical disinfection system only

- **Conclusion**

  In conclusion, Visco Vision Inc. believes that the subject device maintains the same safety and effectiveness as the predicate device and is therefore substantially equivalent.