DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 24, 2016

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

Re: K160245
Trade/Device Name: VISCO (olifilcon A) Soft Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: September 12, 2016
Received: September 14, 2016

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. 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 contact the Division of Industry and Consumer Education 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. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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 Alexander

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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K160245

Device Name
VISCO (olifilcon A) Soft Contact Lens

Indications for Use *(Describe)*
The VISCO (olifilcon A) Toric 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 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 +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.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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## 510(K) SUMMARY

Preparation Date: Sep. 12, 2016

### 1.1 Establishment Information:

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

### 1.2 Contact Person:

| | |
|---|---|
| Company | Jens Medical Consulting Ltd. |
| Name | Jennifer TING |
| Phone No | 886-2-82823192 |
| Fax No | 886-2-82867686 |
| e-mail: | jen.medical@msa.hinet.net |

### 1.3 Device Identification:

| | |
|---|---|
| Proprietary Name | VISCO (olifilcon A) Soft Contact Lens |
| Common Name | Soft (hydrophilic) Contact Lenses |
| Classification Name | Lenses, Soft Contact, Daily Wear<br>(21 CFR 886.5925, Product Code LPL)<br>Lenses, Soft Contact, Daily Wear (Disposable),<br>(21 CFR 886.5925, Product Code MVN) |
| Classification | II |

### 1.4 Legally Marketed Equivalent Device:

| | |
|---|---|
| Predicate Device Name | Biofinity (comfilcon A), K052560, CooperVision Inc.<br>VISCO (olifilcon A), K141348, Visco Vision Inc. |
| Product Code | LPL, MVN |

### 1.5 Device Description

The VISCO (olifilcon A) toric/multifocal soft contact lenses are manufactured in toric or multifocal configurations with UV blocker. The lens material, olifilcon A, is a silicon hydrogel with water content 47%. The VISCO Soft Contact Lens is light blue tinted with “reactive Blue19” for handling visibility purpose. A benzotriazole UV absorbing

monomer is used to block UV radiation. The transmittance characteristics are less than 5% in the UVB range of 280-315nm and less than 50% in the UVA range of 316-380nm. The lens is supplied in a sterile state, packaged in a buffered saline solution containing Sodium Hyaluronate and Sodium Alginate

**1.6 Indication for Use:**

The VISCO (olifilcon A) Toric 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 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 +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.

**1.7 Technological characteristics**

The optical lens design specification:

- Power Range: 20.00D to +20.00D
- Add Power (Multifocal): Low (+0.75D ~ +1.25D)<br>Mid (+1.50D ~ +2.00D)<br>High (+2.25D ~ +2.75D)
- Cylinder Power (Toric): -0.75D, -1.25D, -1.75D, -2.25D<br>Axis from 10° to 180° (in 10° increments)
- Diameter: 13.0 mm to 15.0 mm
- Center Thickness: 0.08mm @ -3.00D (Varies with Power)
- Base Curve: 8.0 mm to 9.2 mm

The physical properties of the lenses are:

- Refractive index: 1.410 (hydrated)
- Light transmittance: > 94%

- Water content: 47% by weight in normal saline
- Oxygen permeability $150 \times 10^{-11}$ $(cm^2/sec)(ml\ O_2/ml.mmHg)$ measured at 35℃ (intrinsic Dk-Colormetric method)

### 1.8 Comparison table:

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

| **Similarities** | | | |
|---|---|---|---|
| **Item** | **Device** | **Predicate (K052560)** | **predicate (K141348)** |
| Product Name | VISCO (olifilcon A) Toric Soft Contact Lens<br>VISCO (olifilcon A) Multifocal Soft Contact Lens | BIOFINITY Toric (comfilcon A) Soft Contact Lens<br>BIOFINITY Multifocal (comfilcon A) Soft Contact Lens | Visco (olifilcon A) soft contact lens |
| Manufacturer | Visco Vision Inc. | CooperVision Inc. | Visco Vision Inc. |
| Intended Use | Myopia, Hyperopia, Prysbyopia | The same | Myopia, Hyperopia |
| Replacement Schedule | Daily wear (monthly) or Daily Disposable (Single use) | daily wear (monthly) or extended wear | Daily wear (monthly) or Daily Disposable (Single use) |
| USAN Name | olifilcon A | comfilcon A | olifilcon A |
| Material | Silicone Hydrogel | Silicone Hydrogel | Silicone Hydrogel |
| Lens Design | toric or multifocal | Spheric, aspheric, toric or multifocal | spheric |
| Classification | Class II, | The same | The same |
| Type | Group I (low water, nonionic) | The same | The same |
| Water Content | 47 % | 48 % | 47% |
| Oxygen Permeability (DK, 35℃) | 150<br>(Fatt method) | 128<br>(Fatt method) | 150<br>(Fatt method) |
| Base Curve Range | 8.0~9.2 | 8.0~9.5 | 8.0~9.2 |
| Diameter (mm) | 13.0~15.0 | 13.5~15.0 | 13.0~15.0 |

| | | | |
|---|---|---|---|
| Center Thickness | Varies with power (0.08 mm at -3.00D) | 0.05 mm – 0.50 mm | Varies with power (0.08 mm at -3.00D) |
| Powers | -20.00D to +20.00D in 0.25 steps | The same | -20.00D to +20.00D in 0.25 steps |
| Add Power (Multifocal) | Low (+0.75D ~ +1.25D)<br>Mid (+1.50D ~ +2.00D)<br>High (+2.25D ~ +2.75D) | +0.50D to +3.00D | NA |
| Cylinder Power (Toric) | -0.75D, -1.25D, -1.75D, -2.25D<br>Axis from 10° to 180° (in 10° increments) | -0.25D -5.00D<br>Axis from 0° to 180° | NA |
| Refractive Index | 1.410 | 1.40 | 1.410 |
| Light Transmittance | 94% | ＞97% | 94% |
| Method of Manufacture | Cast-Molded | The same | The same |
| Surface Treatment | No | No | No |
| Sterilization | steam | The same | The same |
| Packaging | Blister pack | The same | The same |
| Blue handling tint | Yes, reactive Blue19 | Yes, Phthalocyanine Blue | Yes, reactive Blue19 |
| Indication for Use | **Toric**<br>The VISCO (olifilcon A) Toric 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. | **Toric**<br>Biofinity (comfilcon A) toric soft contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -5.00 diopters. | NA |

| | | | |
|---|---|---|---|
| | **Multifocal**<br>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 +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. | **Multifocal**<br>Biofinity (comfilcon A) multifocal lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with add powers from +0.50 to +3.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that 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. | Eye care practitioners may prescribe the lens for frequent replacement wear, with cleaning, disinfecting and scheduled replacements. | Eye care 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 |

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|---|---|---|---|
| | | | disinfection system only.The VISCO Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye. |
| | NA | **Spherical and Aspherical**<br>Biofinity (comfilcon A) sphere and Asphere soft contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. | **Spherical**<br>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. |
| | **NA** | The Biofinity (comfilcon A) soft (hydrophilic) contact lenses have been approved for extended wear for up to 6 nights/7 days of continuous wear. It is recommended that the contact lens wearer first be evaluated on a daily wear schedule. If successful, | |

| | | | |
|---|---|---|---|
| | | then a gradual introduction of extended wear can be followed as determined by the prescribing eye care practitioner. | |

### 1.9 Nonclinical Tests Performed

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

### 1.10 Clinical Studies

The technical characteristic, formulation, manufacturing, and sterilization processes of the subject device are equivalent to the VISCO (olifilcon A) soft contact lens currently available (K 141348). Therefore, the clinical data is not required.

### 1.11 Conclusion

The established safety profile of the device is equivalent to the predicate device, Biofinity (comfilcon A) soft contact lens (K052560), VISCO (olifilcon A) soft contact lens (K141348) in terms of optical property, physical, chemical and pre-clinical toxicology. It is concluded that the lenses are as safe, as effective and perform as well as the predicate devices.