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

May 26, 2016

Visco Vision Inc.
% Ms. Jennifer Ting, Manager
Jens Medical Consulting Ltd.
6F. No. 39, Ln 224, Jixian Rd.
Luzhou Dist. 247 New Taipei City
Taiwan R.O.C

Re: K160344
Trade/Device Name: Si-Hy (olifilcon B) Spherical Silicone Hydrogel Soft Contact Lens; Si-Hy (olifilcon B) Multifocal Silicone Hydrogel Soft Contact Lenses; Si-Hy (olifilcon B) 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: April 20, 2016
Received: April 22, 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)*
K160344

Device Name
Si-Hy (olifilcon B) Silicone Hydrogel Soft (Hydrophilic) Contact Lens

Indications for Use *(Describe)*
The Si-Hy Spherical Silicone Hydrogel Soft Contact Lenses are indicated as daily wear single use 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 Si-Hy 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 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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**005_510(k) Summary**

Preparation Date: May 6, 2016

**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:**

| | |
|---|---|
| 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 |

**5.3 Device Identification:**

| | |
|---|---|
| Proprietary Name | Si-Hy (olifilcon B) Silicone Hydrogel Soft (Hydrophilic) 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:**

**Indication**

Vistakon (narafilcon A), K073485, Product Code: MVN

Johnson & Johnson Vision Care Inc.

**Material**

Visco (olifilcon A) soft contact lens, K141348, Product Code: LPL/MVN

Visco Vision Inc.

**5.5 Device Description**

The Si-Hy (olifilcon B) 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 53% olifilcon B and 47% 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 about 2.2% (＜5%) in the UVB range of 280-315nm and 8.7% (＜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 Si-Hy **Spherical** Silicone Hydrogel Soft Contact Lenses are indicated as daily wear single use 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 Si-Hy **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 **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**

**Si-Hy SPHERICAL** Soft Contact Lenses characteristics:

- Diameter Range：13 to 15 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

**Si-Hy TORIC** Soft Contact Lenses characteristics:

- Diameter Range：13 to 15 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)

**Si-Hy MULTIFOCAL** Soft Contact Lenses characteristics:

- Diameter Range：13 to 15 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.

| **Indication for Use** | | | |
|---|---|---|---|
| Lens Design | Si-Hy (olifilcon B) soft contact lens | VISTAKON (Narafilcon A) Contact lens (K073485) | Visco (olifilcon A) soft contact lens (K141348) |
| Spherical | The Si-Hy **Spherical** Silicone Hydrogel Soft Contact Lenses are indicated as daily wear single use 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 VISTAKON (narafilcon A) contact Lens is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism. | 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. |
| Toric | The Si-Hy **Toric** Silicone Hydrogel Soft Contact Lenses are indicated as daily wear for the correction of ametropia (myopia and hyperopia) with astigmatism in aphakic and | The VISTAKON (narafilcon A) contact Lens is indicated for daily wear single use only for the optical correction of visual acuity in phakic or aphakic | NA |

| | | | |
|---|---|---|---|
| | 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. | persons with non-diseased eyes that are hyperopic or myopic and may have 10.00D or less of astigmatism. | |
| Multifocal | The Si-Hy **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 VISTAKON (narafilcon A) contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic, phakic or aphakic persons with non-diseased eyes who may have 0.75D of astigmatism or less. | NA |
| Multifocal Toric | NA | The VISTAKON (narafilcon A) contact Lens is indicated for daily wear single use only for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with none-diseased eyes who may have 10.00D of astigmatism or less. | NA |
| Replacement | 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. The Si-Hy (olifilcon B) Silicone Hydrogel Soft (Hydrophilic) Contact Lens helps protect against transmission of harmful UV radiation to the cornea and into the eye. | Eye Care Professionals should prescribe the lenses for daily wear single use only (see “Wearing Schedule”). The lenses are to be discarded upon removal. Therefore, no cleaning or disinfection is required. | 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 disinfection system only.The VISCO Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye. |

| Similarities and differences | | | |
|---|---|---|---|
| **Item** | **Device** | **Predicate (**K141348) | **Predicate (**K073485) |
| Product Name | Si-Hy (olifilcon B) Silicone Hydrogel soft contact lens | Visco (olifilcon A) soft contact lens | VISTAKON (Narafilcon A) Contact lens |
| Manufacturer | VISCO VISION Inc. | VISCO VISION Inc. | Johnson & Johnson Vision Care Inc. |
| Intended Use | Myopia, Hyperopia, astigmatism, Presbyopia | Myopia, Hyeropia | Myopia, Hyperopia, astigmatism, Presbyopia |
| Lens Design | Spherical, toric, or multifocal | Spherical | spheric, aspheric, toric or multifocal |
| Replacement Schedule | Daily Disposable (Single use) | Monthly | Daily Disposable (Single use) |
| Chemical composition | Silicone Hydrogel | The same | The same |
| Classification | Group 1 (Nonionic, Low water) | The same | The same |
| Water Content | 47 % (<50%) | 47 % (<50%) | 46 % (<50%), |
| Oxygen Permeability (DK, 35℃) | 120 (Fatt method) | 150 (Fatt method) | 100 (Fatt method) |
| Base Curve Range (mm) | 8.0~9.2 | 8.0~9.2 | 7.80 ~ 10.00 |
| Diameter (mm) | 13.0~15.0 | 13.0~15.0 | 12.0 ~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) | Varies with design and power (0.085 mm at -3.00D) |
| Powers | -20.00D to +20.00D | -20.00D to +20.00D | The same |
| Refractive Index | 1.410 | 1.410 | 1.410 |
| Light Transmittance | 94% | 94% | ＞85% |
| Blue handling tint | Reactive Blue19 | Reactive Blue19 | Reactive Blue Dye #4 |
| Method of Manufacture | Molded | 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 efffectiveness of the Si-Hy (olifilcon B) silicone hydrogel soft contact lens by comparison with Vistakon (narafilcon A) Contact Lens when worn on a daily wear basis. At least 50 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, Vistakon (narafilcon A) soft contact lens, *JOHNSON & JOHNSON VISION CARE INC.* (K073485), 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 “Si-Hy silicone hydrogel soft contact lens” is as safe, as effective and performs as well as the predicate device.