



December 5, 2017

Visco Vision Inc.  
Evan Huang  
Director of Global QA  
No. 1, Xingye St., Guishan Dist.,  
Taoyuan City, 33341 TW

Re: K171447

Trade/Device Name: OxyPure Color Silicone Hydrogel Soft Contact Lenses  
Regulation Number: 21 CFR 886.5925  
Regulation Name: Soft (Hydrophilic) Contact Lens  
Regulatory Class: Class II  
Product Code: LPL, MVN  
Dated: October 23, 2017  
Received: October 31, 2017

Dear Evan Huang:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**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

## Indications for Use

510(k) Number (if known)  
K171447

Device Name

OxyPure Color Silicone Hydrogel Soft Contact Lenses

Indications for Use (Describe)

The OxyPure Color 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.

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.

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.

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## 510(k) Summary

Company Name: Visco Vision Inc  
Company Address: No. 1, Xingye St., Guishan Dist.,  
Taoyuan City, 33341, TAIWAN  
Telephone: +886-3-359-6868  
Fax: +886-3-349-0202  
Contact Person: Evan Huang  
Summary Preparation Date: 2017.4.17

Trade Name: OxyPure Color Silicone Hydrogel Soft Contact Lenses  
Classification: Soft (hydrophilic) contact lens.  
Name: Regulation 886.5925  
Number: Product LPL, MVN  
Code: Device Class 2  
Class: Panel: Ophthalmic

### **PREDICATE DEVICE:**

K141348, VISCO SOFT CONTACT LENS

### **Device Description**

The OxyPure Color Silicone Hydrogel Soft Contact Lenses is a daily wear lens in spherical design. It may be prescribed as daily wear. It is a copolymer of 1-vinyl-2-pyrrolidinone (NVP) and Siloxane macromer. The water content is 47%. A benzotriazole UV absorbing monomer is used to block UV radiation. OxyPure Color Silicone Hydrogel Soft Contact Lenses contain a pigmented area that will alter or enhance the appearance of the natural iris. The lens is colored with one or more of the following color additives: iron oxides, titanium dioxide, phthalocyanine green and carbazole violet. 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.

### **Intended Use:**

The OxyPure Color 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.

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.

All comparison table for applied devices are as following, and the substantial equivalence determination is based on the 510(k) Substantial Equivalence Decision-Making Process Flowchart which includes the comparison and discussion of indications for use, technology, and performance specifications.

| <b>Category</b>   | <b>OxyPure Color Silicone Hydrogel Soft Contact Lenses<br/>New device</b>  | <b>VISCO SOFT CONTACT LENS<br/>K141348</b>  | <b>Result of Comparison</b> |
|-------------------|--|---|-----------------------------|
| Applicant         | Visco Vision Inc   | Visco Vision Inc  | Same                        |
| Classification    | class II   | class II  | Same                        |
| Regulation number | 886.5925   | 886.5925  | Same                        |
| Product code      | LPL, MVN   | LPL, MVN  | Same                        |
| Indication        | Daily Wear or Daily Disposable, Soft (hydrophilic) Contact Lens for Myopia, Hyperopia,   | Daily Wear or Daily Disposable, Soft (hydrophilic) Contact Lens for Myopia  | Same                        |
| Intended use      | The OxyPure Color 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 | 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 | Same                        |

| Category             | <b>OxyPure Color Silicone Hydrogel Soft Contact Lenses</b><br><b>New device</b>   | <b>VISCO SOFT CONTACT LENS K141348</b>   | <b>Result of Comparasion</b> |
|----------------------|---|--|------------------------------|
|                      | <p>exhibit refractive astigmatism of 1.00D or less where the astigmatism does not interfere with visual acuity.</p> <p>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.</p> | <p>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.</p> <p>When prescribed for frequent replacement, the lens may be disinfected using a chemical disinfection system only.</p> <p>The VISCO Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.</p> |                              |
| USAN Name            | Olifilcon A   | Olifilcon A  | Same                         |
| FDA Category (Group) | Group 1<br>Non-ionic, Low water   | Group 1<br>Non-ionic, Low water  | Same                         |
| Manufacturing Method | Cast Molded   | Cast Molded  | Same                         |
| Tint process         | Pad printing  | No Pad Printing  | Different                    |
| Print Zone           | Corresponds to the iris   | N/A  | Different                    |

| Category                       | OxyPure Color Silicone Hydrogel Soft Contact Lenses<br>New device  | VISCO SOFT CONTACT LENS<br>K141348           | Result of Comparasion |
|--------------------------------|--|--|-----------------------|
| Location of printing           | embedded between HEMA (Sandwich Process)   | embedded between HEMA (Sandwich Process)     | Same                  |
| Lens Design                    | Spherical  | Spherical                                    | Same                  |
| Water Content                  | 47%  | 47%  | Same                  |
| Light Transmittance            | > 94%  | > 94%  | Same                  |
| Refractive Index               | 1.410 (hydrated)   | 1.410 (hydrated)                             | Same                  |
| Oxygen Permeability (DK, 35°C) | 150 (Fatt method)  | 150 (Fatt method)                            | Same                  |
| Diameter Range                 | 13 to 15 mm  | 13 to 15 mm                                  | Same                  |
| Power Range                    | - 20.00D to +20.00D in 0.25 steps  | - 20.00D to +20.00D in 0.25 steps            | Same                  |
| Center Thickness               | 0.08mm @ -3.00D (Varies with Power)  | 0.08mm @ -3.00D (Varies with Power)          | Same                  |
| Base Curve                     | 8.0 mm to 9.2 mm   | 8.0 mm to 9.2 mm                             | Same                  |
| Blue handling tint             | No   | Yes, reactive Blue19                         | Different             |
| Color Additives in dye         | <ul style="list-style-type: none"> <li>● Iron oxide</li> <li>● Titanium dioxide</li> <li>● Phthalocyanine green</li> <li>● Carbazole violet</li> </ul> | Reactive Blue19                              | Different             |
| Leachability                   | no leachable monomers and addictive residues   | no leachable monomers and addictive residues | Same                  |
| Single Use                     | No, Frequent/ Planned Replacement  | No, Frequent/ Planned Replacement            | Same                  |
| Packaging                      | Blister Pack   | Blister Pack                                 | Same                  |
| Packaging Solution             | sterile isotonic Borate buffered saline  | sterile isotonic phosphate buffered saline   | Same                  |
| Sterilization method           | Steam  | Steam  | Same                  |

| Category                     | OxyPure Color Silicone Hydrogel Soft Contact Lenses<br>New device | VISCO SOFT CONTACT LENS<br>K141348                     | Result of Comparasion |
|------------------------------|---|--|-----------------------|
| Shelf Life                   | 5 years   | 5 years  | Same                  |
| Sterility of Device          | SAL= 10 <sup>-6</sup>   | SAL= 10 <sup>-6</sup>                                  | Same                  |
| Tensile strength (Mpa)       | 0.78±0.2  | 0.5±0.2  | Different             |
| Modulus (Mpa)                | 0.60 ± 0.1  | 0.60±0.1   | Same                  |
| Elongation at break (%)      | 195 ± 20%   | 100± 20%   | Different             |
| Toughness (J/m3)             | 0.87±0.05   | 0.25±0.05  | Different             |
| <b>Compliance standard</b>   |   |  |                       |
| Biocompatibility             | ISO10993-1<br>ISO10993-5<br>ISO10993-10<br>ISO10993-11            | ISO10993-1<br>ISO10993-5<br>ISO10993-10<br>ISO10993-11 | Same                  |
| Sterilization and Shelf life | ISO 17665-1<br>ISO11737-1<br>ISO 11987                            | ISO 17665-1<br>ISO11737-1<br>ISO 11987                 | Same                  |
| performance                  | ISO18369-3<br>ISO18369-4<br>ISO11986<br>ASTM D792-13              | ISO18369-3<br>ISO18369-4<br>ISO11986<br>ASTM D792-13   | Same                  |

### Substantial Equivalence Comparison

The OxyPure Color Silicone Hydrogel Soft Contact Lenses, and the VISCO SOFT CONTACT LENS have same indication, intended use, classification name/ product code, lens design, lens materials/packaging materials and saline, manufacturing and sterilization method, tint process, performance parameter ranges, physical properties, mechanical properties, biocompatibility and shelf life. The differences between those two devices are mechanical properties and color additives, but other reference devices have same technical characteristic as new devices to support the substantial equivalence.



**Non-clinical tests**

The safety tests, such as biocompatibility have been performed and meet the requirement of following FDA Recognized Consensus Standards.

Regarding the performance, the bench tests were performed in accordance with following FDA Recognized Consensus Standards. All tests passed the requirement to demonstration that new device is as substantial equivalent as the predicate device.

- ISO18369-3 Ophthalmic optics - Contact lenses - Part 3: Measurement Methods
- ISO18369-4 Ophthalmic optics - Contact lenses - Part 4: Physicochemical properties of contact lens materials
- ISO18369-2 Ophthalmic optics - Contact lenses - Part 2: Tolerances
- ISO11986 Ophthalmic optics -- Contact lenses and contact lens care products -- Guidelines for determination of preservation uptake and release
- ISO11987 Ophthalmic optics -- Contact lenses and contact lens care products -- Determination of physical compatibility of contact lens care products with contact lenses
- ISO17665-2 sterilization Of Health Care Products - Moist Heat - Part 2: Guidance on the Application of ISO 17665-1. (Sterility)
- ISO17665-1 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO11980 Ophthalmic optics -- Contact lenses and contact lens care products -- Guidance for clinical investigations
- ASTM D792-13 Standard Test Methods For Density And Specific Gravity (Relative Density) Of Plastics By Displacement. (Materials)

**Clinical study**

This 510(k) submission does not utilize clinical study for establishing substantial equivalence therefore this section does not apply.

**Conclusions:**

OxyPure Color Silicone Hydrogel Soft Contact Lenses has the same intended use and similar technological characteristics as the above predicate devices. Moreover, information contained in this submission supplied demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, OxyPure Color Silicone Hydrogel Soft Contact Lenses is substantially equivalent to the predicate devices with respect to its intended use, technological

characteristics and performance characteristics.