September 13, 2019

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

Re: K183670
Trade/Device Name:
Vexillum Zephyr (olifilcon A) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses
OxyPure A (olifilcon A) 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: August 8, 2019
Received: August 8, 2019

Dear Mr. 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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

for 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

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)*
K183670

Device Name
Vexillum Zephyr (olifilcon A) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses
OxyPure A (olifilcon A) Silicone Hydrogel Soft Contact Lenses

Indications for Use *(Describe)*
The Vexillum Zephyr (olifilcon A) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses are indicated as 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 1.00D 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. The Vexillum Zephyr (olifilcon A) with Tangible Polymers Silicone Hydrogel Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

The OxyPure A (olifilcon A) Silicone Hydrogel Soft Contact Lenses are indicated as 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 1.00D 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. The OxyPure A (olifilcon A) Silicone Hydrogel Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

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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VISCO
The Silicone Hydrogel Expert

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:	2018.10.05

Device Name:

Trade Name:	Vexillum Zephyr (olifilcon A) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses OxyPure A (olifilcon A) Silicone Hydrogel Soft Contact Lenses
Classification Name:	Soft (hydrophilic) contact lens.
Regulation Number:	886.5925
Product Code:	LPL, MVN
Device Class:	Class 2
Panel:	Ophthalmic

PREDICATE DEVICE:
K171447, OxyPure Color Silicone Hydrogel Soft Contact Lenses

Device Description for Vexillum Zephyr (olifilcon A) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses

The Vexillum Zephyr (olifilcon A) with Tangible Polymers Silicone Hydrogel Soft Contact Lens is made of silicone hydrogel material, olifilcon A, with UV blocker available as spherical lens. The composition of the lens is 53% olifilcon A 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 316 - 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 Tangible Polymers (coating on the lens surface during sterilization process) with 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 Vexillum Zephyr (olifilcon A) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses are indicated as 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 1.00D 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. The Vexillum Zephyr (olifilcon A) with Tangible Polymers Silicone Hydrogel Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

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.

Device Description for OxyPure A (olifilcon A) Silicone Hydrogel Soft Contact Lenses

The OxyPure A (olifilcon A) Silicone Hydrogel Soft Contact Lens is made of silicone hydrogel material, olifilcon A, with UV blocker available as spherical lens. The composition of the lens is 53% olifilcon A 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 316 - 380 nm and less than 5% in the range of UVB range of 280-315 nm.

OxyPure A (olifilcon A) Silicone Hydrogel Soft Contact Lenses are supplied sterile in sealed blister packs containing Sodium Hyaluronate and Sodium Alginate with 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 A (olifilcon A) Silicone Hydrogel soft contact lenses are daily wear 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.

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. The OxyPure A (olifilcon A) Silicone Hydrogel Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

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.

Category	**Vexillum Zephyr (olifilcon A) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses New device**	**OxyPure A (olifilcon A) Silicone Hydrogel Soft Contact Lenses New device**	**OxyPure Color Silicone Hydrogel Soft Contact Lenses K171447**	**Result of Comparison**
Applicant	Visco Vision Inc	Visco Vision Inc	Visco Vision Inc	Same
Classification	class II	class II	class II	Same
Regulation number	886.5925	886.5925	886.5925	Same
Product code	LPL, MVN	LPL, MVN	LPL, MVN	Same
Intended use	Myopia, Hyperopia, astigmatism, Presbyopia	Myopia, Hyperopia, astigmatism, Presbyopia	Myopia, Hyperopia, astigmatism, Presbyopia	Same
Replacement	Daily Wear	Daily Wear	Daily Wear	Same

Category	**Vexillum Zephyr (olifilcon A) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses New device**	**OxyPure A (olifilcon A) Silicone Hydrogel Soft Contact Lenses New device**	**OxyPure Color Silicone Hydrogel Soft Contact Lenses K171447**	**Result of Comparison**
Schedule				
USAN Name	olifilcon A	olifilcon A	olifilcon A	Same
FDA Category (Group)	Group 5C (Nonionic, Water < 50 wt %)	Group 5C (Nonionic, Water < 50 wt %)	Group 5C (Nonionic, Water < 50 wt %)	Same
Manufacturing Method	Cast Molded	Cast Molded	Cast Molded	Same
Lens Design	Spherical	Spherical	Spherical	Same
Water Content	47%	47%	47%	Same
Light Transmittance	94%	94%	94%	Same
Refractive Index	1.410 (hydrated)	1.410 (hydrated)	1.410 (hydrated)	Same
Oxygen Permeability (DK, 35℃)	150 (Fatt method)	150 (Fatt method)	150 (Fatt method)	Same
Diameter Range	13.0 to 15.0 mm	13.0 to 15.0 mm	13.0 to 15.0 mm	Same
Power Range	- 20.00D~ +20.00D	- 20.00D~ +20.00D	- 20.00D~ +20.00D	Same
Center Thickness	0.08mm @ -3.00D (Varies with Power)	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	8.0 mm to 9.2 mm	Same
Blue handling tint	Reactive Blue19	Reactive Blue19	No	Different
Color Additives in dye	Reactive Blue19	Reactive Blue19	* Iron oxide * Titanium dioxide * Phthalocyanine green * Carbazole violet	Different
Leachability	no leachable monomers and addictive residues	no leachable monomers and addictive residues	no leachable monomers and addictive residues	Same

Category	**Vexillum Zephyr (olifilcon A) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses New device**	**OxyPure A (olifilcon A) Silicone Hydrogel Soft Contact Lenses New device**	**OxyPure Color Silicone Hydrogel Soft Contact Lenses K171447**	**Result of Comparison**
Packaging	Blister Pack	Blister Pack	Blister Pack	Same
Packaging Solution	sterile isotonic borate buffered saline with Tagible polymers	sterile isotonic borate buffered saline	sterile isotonic borate buffered saline	Different
Coating on the lens surface	Yes, coating with Tangible Polymer during the sterilization process	No	No	Different
Sterilization method	Steam	Steam	Steam	Same
Shelf Life	5 years	5 years	5 years	Same
Sterility of Device	SAL= 10^{-6}	SAL= 10^{-6}	SAL= 10^{-6}	Same
Tensile strength (Mpa)	0.80±0.2	0.80±0.2	0.78±0.2	Different
Modulus (Mpa)	0.60 ± 0.1	0.60 ± 0.1	0.60±0.1	Same
Elongation at break (%)	250± 50	250± 50	195± 20	Diferent
Toughness (J/m3)	1.10±0.05	1.10±0.05	0.87±0.05	Different
Compliance standard				
Biocompatibility	ISO10993-1 ISO10993-5 ISO10993-10 ISO10993-11	ISO10993-1 ISO10993-5 ISO10993-10 ISO10993-11	ISO10993-1 ISO10993-5 ISO10993-10 ISO10993-11	same
Sterilization and Shelf life	ISO 17665-1 ISO11737-1 ISO 11987	ISO 17665-1 ISO11737-1 ISO 11987	ISO 17665-1 ISO11737-1 ISO 11987	Same
performance	ISO18369-3 ISO18369-4 ASTM D792-13	ISO18369-3 ISO18369-4 ASTM D792-13	ISO18369-3 ISO18369-4 ASTM D792-13	Same

Substantial Equivalence Comparison

The Vexillum Zephyr (olifilcon A) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses, The OxyPure A (olifilcon A) Silicone Hydrogel Soft Contact Lenses, and OxyPure Color Silicone Hydrogel Soft Contact Lens, have same Lens design, intended use, Replacement Schedule, classification name/product code, len materials, manufacturing and sterilization method, perfomance parameter ranges, mechanical properties, physical properties, mechanical properties, biocompatibility, shelf life and other reference devices have same technical characteristic as new devices to support the substantial equivalence. The differences among those three devices are Blue handling tint, Color Additives in dye, Packaging Solution, Coating on the lens surface, Tensile strength, Elongation at break and Toughness.

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
- ISO11987 Ophthalmic optics -- Contact lenses and contact lens care products -- Determination of physical compatibility of contact lens care products with contact lenses
- ISO17665-2 terilization 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
- 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:

Vexillum Zephyr (olifilcon A) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses and OxyPure A (olifilcon A) Silicone Hydrogel Soft Contact Lenses have the same Lens design,intended use and technological characteristics as the above predicate devices. Moreover, information contained in this submission supplied demonstrates that any differences in their Blue handling tint, Color Additives in dye, packing solution, Coating on the lens surface , Tensile strength, Elongation at break and Toughness do not raise any new questions of safety or effectiveness. Thus, Vexillum Zephyr (olifilcon A) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses and OxyPure A (olifilcon A) Silicone Hydrogel Soft Contact Lenses are substantially equivalent to the predicate devices with respect to its intended use, technological characteristics and performance characteristics.