September 19, 2018

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

Re: K181349
Trade/Device Name: Vexillum (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses; Daily Breeze (olifilcon B) 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 27, 2018
Received: August 27, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

J. Angelo Green

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181349

Device Name
Vexillum (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses
Daily Breeze (olifilcon B) Silicone Hydrogel Soft Contact Lenses

Indications for Use *(Describe)*

The Vexillum (olifilcon B) with Tangible Polymers Spherical Silicone Hydrogel Soft Contact Lenses are daily wear single use soft contact lenses 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.

The Vexillum (olifilcon B) with Tangible Polymers Toric Silicone Hydrogel Soft Contact Lenses are indicated as daily wear single use soft contact lenses 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 Vexillum (olifilcon B) with Tangible Polymers Multifocal Silicone Hydrogel Soft Contact lenses are indicated as daily wear single use soft contact lenses 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.

The Daily Breeze (olifilcon B) Spherical Silicone Hydrogel Soft Contact Lenses are daily wear single use soft contact lenses indicated for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who exhibit refractive astigmatism of 1.00 diopters or less where the astigmatism does not interfere with visual acuity.

The Daily Breeze (olifilcon B) 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 Daily Breeze (olifilcon B) 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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VISCO
The Silicone Hydrogel Expert

510(k) Summary--K181349

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:	2018.5.15

Device Name:

Trade Name:	Vexillum (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses Daily Breeze (olifilcon B) 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:

K160344, Si-Hy (olifilcon B) Silicone Hydrogel Soft (Hydrophilic) Contact Lenses

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

The Vexillum (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lens is made of silicone hydrogel material, olifilcon B, 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” 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 (olifilcon B) with Tangible Polymers **Spherical** Silicone Hydrogel soft contact lenses are daily wear single use soft contact lens 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.

The Vexillum (olifilcon B) with Tangible Polymers **Toric** Silicone Hydrogel Soft Contact Lenses are indicated as daily wear single use 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 -20.00 to +20.00 diopters and astigmatic corrections are from -0.75 to -2.25 diopters.

The Vexillum (olifilcon B) with Tangible Polymers **Multifocal** Silicone Hydrogel Soft Contact lenses are indicated as daily wear single use 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 -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 dscarded upon removal. Therefore, no cleaning or disinfecting is requried.

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 Daily Breeze (olifilcon B) Silicone Hydrogel Soft Contact Lenses

The Daily Breeze (olifilcon B) Silicone Hydrogel Soft Contact Lens is made of silicone hydrogel material, olifilcon B, 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” 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 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 Daily Breeze (olifilcon B) **Spherical** Silicone Hydrogel soft contact lenses are daily wear single use soft contact lens 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.

The Daily Breeze (olifilcon B) **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 Daily Breeze (olifilcon B) **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 dscarded upon removal. Therefore, no cleaning or disinfecting is requried.

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.

VISCO
The Silicone Hydrogel Expert

Category	Vexillum (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses New device	Daily Breeze (olifilcon B) Silicone Hydrogel Soft Contact Lenses New device	Si-Hy (olifilcon B) Silicone Hydrogel Soft Contact Lenses K160344	Result of Comparasion
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 Schedule	Daily Disposable (Single use)	Daily Disposable (Single use)	Daily Disposable (Single use)	same
USAN Name	olifilcon B	olifilcon B	olifilcon B	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, toric or multifocal	Spherical, toric or multifocal	Spherical, toric or multifocal	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℃)	120 (Fatt method)	120 (Fatt method)	120 (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	Reactive Blue19	same

Category	**Vexillum (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses New device**	**Daily Breeze (olifilcon B) Silicone Hydrogel Soft Contact Lenses New device**	**Si-Hy (olifilcon B) Silicone Hydrogel Soft Contact Lenses K160344**	**Result of Comparasion**
Leachability	no leachable monomers and addictive residues	no leachable monomers and addictive residues	no leachable monomers and addictive residues	same
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	0.80±0.2	same
Modulus (Mpa)	0.50 ± 0.1	0.50 ± 0.1	0.50±0.1	same
Elongation at break (%)	200± 20%	200± 20%	200± 20%	same
Toughness (J/m3)	0.90±0.05	0.90±0.05	0.90±0.05	same
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	ISO18369-3	ISO18369-3	Same

Category	Vexillum (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses New device	Daily Breeze (olifilcon B) Silicone Hydrogel Soft Contact Lenses New device	Si-Hy (olifilcon B) Silicone Hydrogel Soft Contact Lenses K160344	Result of Comparasion
	ISO18369-4 ASTM D792-13	ISO18369-4 ASTM D792-13	ISO18369-4 ASTM D792-13	

Substantial Equivalence Comparison

The Vexillum (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses, The Daily Breeze (olifilcon B) Silicone Hydrogel Soft Contact Lenses, and the The Si-Hy (olifilcon B) Silicone Hydrogel Soft Contact Lenses, have same intended use, Replacement Schedule, classification name/product code, len materials, manufacturing and sterilization method, perfomance parameter ranges, lens design, mechanical properties, physical properties, mechanical properties, biocompatibility, shelf life, Elongation at break and other reference devices have same technical characteristic as new devices to support the substantial equivalence. The differences among those three devices are Packaging Solution and Coating on the lens surface.

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 (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses and Daily Breeze (olifilcon B) Silicone Hydrogel Soft Contact Lenses have the same intended use and technological characteristics as the above predicate devices. Moreover, information contained in this submission supplied demonstrates that any differences in their packing solution and Coating on the lens surface do not raise any new questions of safety or effectiveness. Thus, Vexillum (olifilcon B) with Tangible Polymers Silicone Hydrogel Soft Contact Lenses and Daily Breeze (olifilcon B) Silicone Hydrogel Soft Contact Lenses are substantially equivalent to the predicate devices with respect to its intended use, technological characteristics and performance characteristics.