July 15, 2020

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

Re: K201080
Trade/Device Name: Daily Breeze B (olifilcon B) Spherical Silicone Hydrogel Soft Contact Lens,
Daily Breeze B (olifilcon B) Toric Silicone Hydrogel Soft Contact Lens,
Daily Breeze B (olifilcon B) Multifocal 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 17, 2020
Received: April 22, 2020

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/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,

J. 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)*
K201080

Device Name
Daily Breeze B (olifilcon B) Spherical Silicone Hydrogel Soft Contact Lens
Daily Breeze B (olifilcon B) Toric Silicone Hydrogel Soft Contact Lens
Daily Breeze B (olifilcon B) Multifocal Silicone Hydrogel Soft Contact Lens

Indications for Use *(Describe)*

The Daily Breeze B (olifilcon B) Spherical Silicone Hydrogel Soft Contact Lens is indicated as daily wear and 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 1.00 D or less here the astigmatism does not interfere with visual acuity.

The Daily Breeze B (olifilcon B) Toric Silicone Hydrogel Soft Contact Lenses are indicated as daily wear and single use 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 -12.00 to +8.00 D and astigmatism corrections are from -0.75 to -2.25 D.

The Daily Breeze B (olifilcon B) Multifocal Silicone Hydrogel Soft Contact Lenses are indicated as daily wear and single use 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 -12.00 to +8.00 D with add powers from +0.25 to +2.75 D. The lenses may be worn by persons who exhibit astigmatism of 1.00 D or less where the astigmatism does not interfere with visual acuity.

Eyecare practitioners prescribe the lens for single-use disposable wear.

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

K201080

1. Establishment Information:

Company Name:	Visco Vision Inc
Company Address:	No. 1, Xingye St., Guishan Dist., Taoyuan City, 33341, TAIWAN
Telephone:	+886-3-359-6868
Fax:	+886-3-359-6868

2. Contact Person:

Name:	Evan Huang
P hone No.	886-3-3596868
Fax No.	886-3-3490202
E-mail:	evan.huang@viscovision.com.tw

3. Preparation Date: 2020/04/08

4. Device Identification:

Classification Name:	Soft (hydrophilic) contact lens.
Regulation Number:	886.5925
Product Code:	LPL, MVN
Device Class:	Class 2
Panel:	Ophthalmic
Device Name:	Daily Breeze B (olifilcon B) Silicone Hydrogel Soft Contac Lens
Trade Name:	Daily Breeze B (olifilcon B) Spherical Silicone Hydrogel Soft Contact Lens Daily Breeze B (olifilcon B) Toric Silicone Hydrogel Soft Contac Lens Daily Breeze B (olifilcon B) Multifocal Silicone Hydrogel Soft Contac Lens

5. Predicate Device:

- K160344, Si-Hy (olifilcon B) Silicone Hydrogel soft contact lens

6. Device Description

The Daily Breeze B (olifilcon B) Silicone Hydrogel Soft Contact Lens is made of 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, which is a copolymer of 1-vinyl-2-pyrrolidinone (NVP) and Siloxane macromer, 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 315 - 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 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.

7. Indications for Use:

The Daily Breeze B (olifilcon B) **Spherical** Silicone Hydrogel Soft Contact Lens is indicated as daily wear and 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 Daily Breeze B (olifilcon B) **Toric** Silicone Hydrogel Soft Contact Lenses are indicated as daily wear and single-use 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 -12.00 to +8.00 diopters and astigmatic corrections are from -0.75 to -2.25 diopters.

The Daily Breeze B (olifilcon B) **Multifocal** Silicone Hydrogel Soft Contact lenses are indicated as daily wear and single-use 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 -12.00 to +8.00 diopters with add powers from +0.25 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.

Eyecare practitioners prescribe the lens for single-use disposable wear.

8. Technological characteristic

8.1 Daily Breeze B (olifilcon B) Silicone Hydrogel Soft Contact Lenses characteristics:

- Diameter Range： 13.0 to 15.0 mm, ±0.2mm
- Base Curve： 8.0 to 9.2 mm, ±0.2mm
- Center Thickness： 0.09 mm for -3.00D (varies with power), ± [0.010 mm + 0.10 tc]

- Power： +8.00 to -12.00 D (|F ´ L| ≤ 10,00 D: ±0.25D; 10,00 D < |F ´ L| ≤ 20,00 D: ±0.50D)

8.2 Daily Breeze B (olifilcon B) Toric Silicone Hydrogel Soft Contact Lenses characteristics:

- Diameter Range： 13.0 to 15.0 mm, ±0.2mm
- Base Curve： 8.0 to 9.2 mm, ±0.2mm
- Center Thickness： 0.09 mm for -3.00D (varies with power), ± [0.010 mm + 0.10 tc]
- Power： +8.00 to -12.00 D(|F ´ L| ≤ 10,00 D: ±0.25D; 10,00 D < |F ´ L| ≤ 20,00 D: ±0.50D)
- Cylinder: -0.75D ~ -2.25D
- Axis: 10° to 180° (in 10° increments)

8.3 Daily Breeze B (olifilcon B) Multifocal Silicone Hydrogel Soft Contact Lenses characteristics:

- Diameter Range： 13.0 to 15.0 mm, ±0.2mm
- Base Curve： 8.0 to 9.2 mm , ±0.2mm
- Center Thickness： 0.09 mm for -3.00D (varies with power), ± [0.010 mm + 0.10 tc]
- Power： +8.00 to -12.00 D (|F ´ L| ≤ 10,00 D: ±0.25D; 10,00 D < |F ´ L| ≤ 20,00 D: ±0.50D)
- Additional Powers: +0.25D ~ +2.75D

9. Substantial Equivalence Comparison

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	**Daily Breeze B (olifilcon B) Silicone Hydrogel Soft Contact Lens**	**Si-Hy (olifilcon B) Silicone Hydrogel soft contact lens**	**Result of Comparison**
Applicant	Visco Vision Inc	Visco Vision Inc	Same
Indications for use	The Daily Breeze B (olifilcon B) Silicone Hydrogel Soft Contact Lens are indicated as daily wear single use soft contact lens for	The Si-Hy (olifilcon B) Silicone Hydrogel soft contact lens are indicated as daily wear single use soft contact lens for the correction of refractive	Same

Category	**Daily Breeze B (olifilcon B) Silicone Hydrogel Soft Contact Lens**	**Si-Hy (olifilcon B) Silicone Hydrogel soft contact lens**	**Result of Comparison**
	the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes	ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes	
Classification	class II	class II	Same
Regulation number	886.5925	886.5925	Same
Product code	MVN	MVN	Same
Intended use	Myopia, Hyperopia, astigmatism, Presbyopia	Myopia, Hyperopia, astigmatism, Presbyopia	Same
Replacement Schedule	Daily Disposable (Single use)	Daily Disposable (Single use)	Same
USAN Name	olifilcon B	olifilcon B	Same
FDA Category (Group)	Group 5C (Nonionic, Water < 50 wt %)	Group 5C (Nonionic, Water < 50 wt %)	Same
Manufacturing Method	Molded	Molded	Same
Lens Design	Spherical, toric, or multifocal	Spherical, toric, or multifocal	Same
Water Content	47 % (<50%)	47 % (<50%)	Same
Light Transmittance	94%	94%	Same
Refractive Index	1.410	1.410	Same
Oxygen Permeability (DK, 35℃)	120 (Fatt method)	120 (Fatt method)	Same
Diameter Range (mm)	13.0~15.0	13.0~15.0	Same
Power Range	+8.00 to -12.00 D	-20.00D to +20.00D	Different
Center Thickness	0.09mm @ -3.00D (Varies with Power)	0.08mm @ -3.00D (Varies with Power)	Different
Base Curve (mm)	8.0~9.2	8.0~9.2	Same
Blue handling tint	Reactive Blue19	Reactive Blue19	Same
Sterilization	Steam Sterilization	Steam Sterilization	Same

10. Non-clinical tests

10.1 Biocompatibility

The safety tests, such as biocompatibility have been performed in accordance with ISO10993. Toxicology studies report shows that the lenses are non-toxic and biocompatibility result is acceptable in ocular environment.

10.2 Sterilization and Stability Testing

- 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
- ISO 11987 Ophthalmic optics-Contact lenses-Determination of shelf-life.

10.3 Performance Data

Physiochemical studies were conducted according to ISO 18369 Ophthalmic optics - Contact lenses (Ophthalmic). The physical, optical and chemical properties of the lens are within established specifications for the lenses.

- 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

11. Clinical study

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

12. Conclusions:

Daily Breeze B (olifilcon B) Silicone Hydrogel Soft Contact Lens and Si-Hy (olifilcon B) Silicone Hydrogel soft contact lens have the same manufacturing process, operating principles, sterilization and materials as the above predicate devices. Being similar with respect to the physical/chemical/optical amd performance characteristic to the predicated deice, this meets the *Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses,May 1994*, the information provided herein supports the claim of substantial equivalence. it shows that “Daily Breeze B (olifilcon B) Silicone Hydrogel Soft Contact Lens” is as safe, as effective and performs as well as the predicate device.