December 7, 2020

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

Re: K200618
Trade/Device Name: HydroSens A (hioxifilcon A) Spherical 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: October 28, 2020
Received: November 2, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200618

Device Name
HydroSens A (hioxifilcon A) Spherical Hydrogel Soft Contact Lens

Indications for Use *(Describe)*
HydroSens A (hioxifilcon A) Spherical Hydrogel Soft Contact Lens are daily disposable 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.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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: 2020/03/04

4. Device Identification:

Common or usual name	Hydrogel Soft Contact Lens
Classification Name	Soft (hydrophilic) contact lens
Regulation Number	886.5925
Product Code	LPL,MVN
Device Class	Class 2
Panel	Ophthalmic
Device Name	HydroSens A (hioxifilcon A) Hydrogel Soft Contact Lens
Trade Name:	HydroSens A (hioxifilcon A) Spherical Hydrogel Soft Contact Lens

5. Predicate Device:

- K040303, 59% Extreme H2O (hioxifilcon A) Soft Contact Lens for Daily Wear (cast-molded, with a visibility tint)
- K992692, 59% extreme H2O® soft contact lens

6. Device Description

The HydroSens A (hioxifilcon A) Hydrogel Soft Contact Lens is made of hydrogel material, hioxifilcon A, with UV blocker available as spherical lens. The composition of the lens is 43% hioxifilcon A and 57% water. A light blue color tinted with “reactive Blue19” listed in 21 CFR Part 73.3121 is for handling visibility purpose. 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 MPC polymer (2-(Methacryloyloxy) ethyl 2-(trimethylammonio) ethyl phosphate-n-butyl methacrylate copolymer) 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.

7. Intended Use:

The HydroSens A (hioxifilcon A) Spherical Hydrogel Soft Contact Lens are daily disposable 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.

8. Technological characteristic

8.1 HydroSens A (hioxifilcon A) Spherical Hydrogel Soft Contact Lens characteristics:

- Diameter Range： 13.0 to 15.0 mm, ±0.2mm
- Base Curve： 8.0 to 9.2 mm, ±0.2mm
- Center Thickness： 0.08 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)

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	HydroSens A (hioxifilcon A) Hydrogel Soft Contac Lens	59% extreme H2O® soft contact lens (K992692)	59% Extreme H2O (hioxifilcon A) Soft Contact Lens for Daily Wear (cast-molded, with a visibility tint) (K040303)	Result of Comparison
Indications for use	HydroSens A (hioxifilcon A) Spherical Hydrogel Soft Contact Lens are daily disposable 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.	59% extreme H2O® soft contact lens for daily Wear are indicated for correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit refractive astigrmatism of 0.75 Diopters or less that does not interfere with visual acuity. The lens are avaliable clear and with a blue visbility handling tint. Eyecare practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected	The 59% Extreme H_20 (hioxifilcon A) toric soft contact lens for daily wear is indicated for the correction of visual acuity in aphakic or not-aphakic persons with non-diseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit astigmatism of 10.00 Diopters or less. Eye care practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system.	The main indication are same, the minor difference does not interfere with the effectiveness or safety of lens

		using either a heat and chemical disinfection system.		
Applicant	Visco Vision Inc	Benz Research and Development INC.	Hydrogel Vision Corporation	Different
Classification	Class II	Class II	Class II	Same
Regulation number	886.5925	886.5925	886.5925	Same
Product code	LPL,MVN	LPL	LPL	Different
Intended use	Myopia, Hyperopia,	Myopia, Hyperopia	Myopia, Hyperopia, astigmatism	Different
Replacement Schedule	Daily Disposable	Daily Wear	Daily Wear	Different
USAN Name	hioxifilcon A	hioxifilcon A	hioxifilcon A	Same
FDA Category (Group)	Group #2 >50% Water, non-ionic Polymer	Group #2 >50% Water, non-ionic Polymer	Group #2 >50% Water, non-ionic Polymer	Same
Manufacturing Method	Cast Molded	Cast Molded	Cast Molded	Same
Lens Design	Spherical	Spherical	Spherical,Toric	Different
Water Content	57%	59%	59%	Different
Light Transmittance	95%	95%	95%	Same
Refractive Index	1.402 (hydrated)	1.404 (hydrated)	1.404 (hydrated)	Different
Oxygen Permeability (DK, 35°C)	$22x10^{-11}(cm_2/sec)$(ml O2/ml x mmHg @ 35°C)	$18x10^{-11}(cm_2/sec)$(ml O2/ml x mmHg @ 35°C)	$18x10^{-11}(cm_2/sec)$(ml O2/ml x mmHg @ 35°C)	Different
Specific Gravity	1.1300(hydrated)	1.136 (hydrated)	1.136 (hydrated)	Different
Sterilization	Steam Sterilization	Steam Sterilization	Steam Sterilization	Same
Modulus	0.38 Mpa	-	0.34 Mpa	Different
Tensile strength	35.0 gf/mm^2	-	36 gf/mm^2	Different
Elongation at break	108%	-	128%	Different

Toughness	0.210 J/m^3	-	0.215 J/m^3	Different

10. Non-clinical tests

10.1 Biocompatibility

The safety tests, such as biocompatibility have been performed in accordance with Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses, May 1994 and GLP regulation (21 CFR part 58) and relevant ISO 10993 series biocompatibility standard. The biocompatibility report indicates that each test article (lens extracts from the final sterilized blister packaging , packaging buffer solution, extracts of packaging material (Al foil and PP blister)) does not negatively impact the safety of the devices and all of them are non-toxic and biocompatible.

These tests include: cytotoxicity, acute systemic toxicity, ocular irritation and skin sensitization testing. Biocompatibility testing performed includes the following referenced standards

- ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

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:

HydroSens A (hioxifilcon A) Hydrogel Soft Contact Lens and 59% extreme H2O® soft contact lens, 59% Extreme H2O (hioxifilcon A) Soft Contact Lens for Daily Wear (cast-molded, with a visibility tint) have the same manufacturing process, operating principles, sterilization and materials as the above predicate devices. Being similar with respect to the physical, chemical, optical, mechanical property and 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 “HydroSens A (hioxifilcon A) Hydrogel Soft Contact Lens” is as safe, as effective and performs as well as the predicate device.