May 13, 2022

Innova Vision Inc.
Kari Huang
Official Correspondent
2F., No. 20, Prosperity Rd. 1, Hsinchu Science Park
Hsinchu, 300091
Taiwan

Re: K213119
Trade/Device Name: Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: April 1, 2022
Received: April 4, 2022

Dear Kari 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)*
K213119

Device Name
Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens

Indications for Use *(Describe)*

Sphere/Asphere

Innova Vision Sphere and Asphere (Hioxifilcon A) Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Toric

Innova Vision Toric (Hioxifilcon A) Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

Multifocal

Innova Vision Multifocal (Hioxifilcon A) Soft Contact lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with add powers from +0.25 to +4.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Multifocal Toric

Innova Vision Multifocal Toric (Hioxifilcon A) Soft Contact lenses are indicated for the optic correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes in powers of -20.00 to +20.00 diopters with add powers from +0.25 to +4.00 diopters and astigmatism corrections from -0.25 to -10.00 diopters.

Eye Care Practitioners may prescribe the Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement or for single-use disposable wear.

When prescribed for frequent/planned replacement, the Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens is to be cleaned, rinsed and disinfected each time the lens is removed. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection only.

When prescribed for single-use disposable wear, Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens is to be discarded after each removal.

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

1 Type of Submission: Traditional

2 Date of Summary: 09/17/2021

3 Submitter: Innova Vision Inc.

Address: 2F., No. 20, Prosperity Rd. 1, Hsinchu Science Park 300091, Taiwan

Phone: +886-3-5927299

Contact: Kari Huang (karihuang@innovavision.com.tw)

4 Identification of the Device:

Proprietary/Trade name:	Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens
Classification Product Code:	LPL
Subsequent Product Code:	MVN
Regulation Number:	886.5925
Regulation Description:	Soft (hydrophilic) contact lens
Review Panel:	Ophthalmic
Device Class:	II
Basis for the Submissions	New Device

5 Identification of the Predicate Device:

Predicate Device Name:	Clalen 58 (hioxifilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
Applicant:	Interojo, Inc.
Classification Product Code:	LPL, MVN
Regulation number:	886.5925
Device Class:	II
510(k) Number:	K153766

6 Identification of the Reference Device:

Reference Device Name:	UNICON Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens
Applicant:	UNICON Optical CO.,LTD
Classification Product Code:	LPL, MVN
Regulation number:	886.5925
Device Class:	II
510(k) Number:	K191929

7 Indications for Use / Intended Use of the Device

Sphere/Asphere

Innova Vision Sphere and Asphere (Hioxifilcon A) Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Toric

Innova Vision Toric (Hioxifilcon A) Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

Multifocal

Innova Vision Multifocal (Hioxifilcon A) Soft Contact lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with add powers from +0.25 to +4.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Multifocal Toric

Innova Vision Multifocal Toric (Hioxifilcon A) Soft Contact lenses are indicated for the optic correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes in powers of -20.00 to +20.00 diopters with add powers from +0.25 to +4.00 diopters and astigmatism corrections from -0.25 to -10.00 diopters.

Eye Care Practitioners may prescribe the Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement or for single-use disposable wear.
When prescribed for frequent/planned replacement, the Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens is to be cleaned, rinsed and disinfected each time the lens is removed. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection only.
When prescribed for single-use disposable wear, Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens is to be discarded after each removal.

8 Description of the Device

Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens is available as spherical and aspherical lenses manufactured by cast-molding method. The material is a high water content (59% wt/wt) material. The hydrogel lens' material is a random copolymer of 2-hydroxyethyl methacrylate (HEMA) and glycerol methacrylate (GMMA) cross-linked with ethylene glycol dimethacrylate (EGDMA) via UV photo-polymerization. Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens is tinted with Reactive Blue 19 to enhance the visibility for handling and contains 2-[3-(2H-Benzotriazol-2-yl)-4-hydroxyphenyl] ethyl methacrylate as an additive for ultraviolet blocking purpose. The average transmittance in the UVB region is less than 5% and less than 50% in the UVA region.

The properties of the lens are:

- Chord Diameter: 13.00 mm to 15.00 mm
- Center Thickness 0.080 mm to 0.580 mm
- Base Curve: 8.0 mm to 9.8 mm
- Power Range
  - Sphere Power: -20.00 D to +20.00 D in 0.25 D steps
  - Cylinder Power (Toric): -0.25 D to -2.25 D in 0.25 D steps
  - Cylinder Axis (Toric): 10° to 180° in 10° steps
  - Multifocal Power: +0.25 D to +4.00 D in 0.25D steps
- Specific Gravity: 0.98 to 1.12
- Refractive Index: 1.400 ± 0.005
- Visible Light Transmittance: > 95%
- UVA (315 nm~380 nm) Absorbance > 50%
- UVB (285 nm~315 nm) Absorbance > 95%
- Surface Character: Hydrophilic
- Water Content: 59% ± 2%
- Oxygen Permeability: $25 \times 10^{-11}(cm^2/s)/(ml\ O_2/[ml \cdot mmHg]) \pm 20\%$

9 Non-clinical Testing

A series of non-clinical safety and performance studies were conducted on the subject device. The following tests and studies were according to the FDA guidance "Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses, Issued May 1994" and related recognized consensus standards. All the test results met the requirements of products specification.

- Sterilization validation and Shelf life

  Test results demonstrated that subject device complies with ISO 11138-1, ISO 11138-3, ISO 11137-1, ISO 11137-2, ISO 17665-1, ASTM F1929-15, ISO 18369-3, ISO 11987, ISO 11737-2 and ASTM F2338-09 requirements.

- Biocompatibility

  Test results demonstrated that subject device complies with ISO 10993-1, ISO 10993-5, ISO 10993-12, ISO 10993-10, ISO 10993-11 and ASTM F750-87 requirements.

- Performance
  - Oxygen Permeability
  - Tensile Strength
  - Refractive Index
  - Water Content
  - Specific Gravity
  - Extractables
  - Luminous Transmittance
  - Lens Compatibility with Multi-Purpose Solution
  - Osmolality Determination
  - pH Value Determination
  - Geometric Parameters

  Test results demonstrated that subject device complies with ISO 18369-4, ASTM D882-18, ASTM D1708-18 and ISO 18369-3 requirements.

10 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence. The safety and effectiveness of finished contact lenses have been established through previous non-clinical performance testing.

11 Substantial Equivalence Determination

The Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens submitted in this 510(k) file is substantially equivalent in intended use, main materials, and safety and performance claims to the cleared device, Clalen 58 (hioxifilcon A)

Soft (hydrophilic) Contact Lens For Daily Wear (K153766) and UNICON Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens (K191929). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	Subject device	Predicate device	Reference device	Substantial Equivalence Discussion
Manufacturer	Innova Vision Inc.	Interojo, Inc.	UNICON Optical CO.,LTD	
Trade Name	Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens	Clalen 58 (hioxifilcon A) Soft (hydrophilic) Contact Lens for Daily Wear	UNICON Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens	
510(k) No.	(to be assigned)	K153766	K191929	
Indications For Use	**Sphere/Asphere** Innova Vision Sphere and Asphere (Hioxifilcon A) Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. **Toric** Innova Vision Toric (Hioxifilcon	The **Clalen 58 (hioxifilcon A)** Spherical Soft Contact Lenses for daily wear are indicated for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted for visibility and handling. The **Clalen 58 (hioxifilcon A) Toric** Soft Contact Lens for daily	The Unicon Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens is indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and 6.00 diopters (D) or less of astigmatism. Eye Care Professionals may prescribe the lenses either for single-use disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement.	***Equivalent*** The main indication is the same, and the few different wordings do not affect the equivalence.

	A) Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters. **Multifocal** Innova Vision Multifocal (Hioxifilcon A) Soft Contact lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and with add powers from +0.25 to +4.00 diopters. The lenses may be worn by persons who	wear are indicated for the correction of refractive error in aphakic persons with non-diseased eyes with myopia or hyperopia and/or possess refractive astigmatism not exceeding 5.00 diopters. The lens is available clear or tinted for visibility and handling. The **Clalen 58 (hioxifilcon A) Multifocal** Soft Contact Lenses for daily wear are indicated for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by presbyopic persons requiring an add power ranging from +1.25D to +2.50D, and who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity.	When prescribed for daily disposable wear, the lens is to be discarded after each removal. When prescribed for frequent/planned replacement, the lens may be cleaned and disinfected using a chemical disinfection system only.	

	exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. **Multifocal Toric** Innova Vision Multifocal Toric (Hioxifilcon A) Soft Contact lenses are indicated for the optic correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes in powers of -20.00 to +20.00 diopters with add powers from +0.25 to +4.00 diopters and astigmatism corrections from -0.25 to -10.00 diopters. Eye Care Practitioners may prescribe the Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement or for	The lens is available clear or tinted for visibility and handling. The **Clalen 58 (hioxifilcon A)) Toric-Multifocal** Soft Contact Lenses for daily wear are indicated for the correction of refractive error in aphakic and not aphakic persons with nondiseased eyes with myopia or hyperopia, possesses refractive astigmatism not exceeding 5.00 diopters. The lens may be worn by presbyopic persons requiring an add power ranging from +1.25D to +2.50D. The lens is available clear or tinted for visibility and handling. Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.		

	single-use disposable wear. When prescribed for frequent/planned replacement, the Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens is to be cleaned, rinsed and disinfected each time the lens is removed. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection only. When prescribed for single-use disposable wear, Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens is to be discarded after each removal.	Frequent/Planned Replacement Wear: Eyecare practitioners may prescribe any of the above lenses 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 disinfecting system. Disposable Wear: Eyecare practitioners may prescribe any of the above lenses for single use daily disposable wear. When Prescribed for daily disposable wear the lens is to be discarded after each removal.		

Item	Subject device	Predicate device	Reference device	Substantial Equivalence Discussion
Manufacturer	Innova Vision Inc.	Interojo, Inc.	UNICON Optical CO.,LTD	
Trade Name	Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens	Clalen 58 (hioxifilcon A) Soft (hydrophilic) Contact Lens For Daily Wear	UNICON Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens	
510(k) No.	(to be assigned)	K153766	K191929	
Type of Use	Prescription Use	Prescription Use	Prescription Use	***Same***
UV blocking	Yes	Yes	Yes	***Same***
Production Method	Cast-molded	Fully molded	Cast-molded	***Same***
USAN Name	Hioxifilcon A	Hioxifilcon A	Hioxifilcon A	***Same***
Water Content	59 ± 2%	59 ± 2%	59 ± 2%	***Same***
Oxygen Permeability	25 × 10-11(cm^2/s)/(ml O^2/[ml•mmHg]) ± 20%	20.76 × 10^{-11}(cm^2/sec) (mlO_2/ml x mm Hg)	25 × 10^{-11}(cm^2/sec) (mlO_2/ml*mmHg)	***Equivalent*** Not significantly different and meets the requirement; therefore it would not affect the equivalence.
Refractive Index	1.400 ± 0.05	1.403 (hydrated)	1.404 (hydrated)	***Equivalent*** Not significantly different and meets the requirement; therefore it would not affect the equivalence.

12 Similarity and Difference

The Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens is compared with *Clalen 58 (hioxifilcon A) Soft (hydrophilic) Contact Lens for Daily Wear* and *UNICON Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens*. The subject device has same intended use and technology/mechanism of action, and similar safety and performance as the predicate device and reference device. No specifications are significantly different between these three devices.

Furthermore, the subject device has undergone other safety and performance tests, and the results complied with the testing guidance. Therefore, any differences between the subject device, the predicate device and reference device are insignificant and do not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate device and reference device in intended use, design and performance claims.

13 Conclusion

After analyzing non-clinical laboratory studies, safety and performance testing data, it can be concluded that the Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens is substantially equivalent to the predicate device and reference device.