September 17, 2019

UNICON Optical CO., LTD
Hsiao-Wei Shen
Coordinator
No 16, Gongye E. 9th Rd.
Hsinchu Science Park, Baoshan Township
Hsinchu County, TW 30075

Re: K191929
Trade/Device Name: UNICON 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: July 16, 2019
Received: July 19, 2019

Dear Mr. Shen:

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)*

K191929

Device Name
UNICON Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens

Indications for Use *(Describe)*
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. When prescribed for daily disposable wear, the lens is to be discarded after each removal. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical disinfection system only.

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

5.1 Type of Submission: Traditional

5.2 Date of Summary: 07/16/2019

5.3 Submitter:

Address:	No 16, Gongye E. 9th Rd., Hsinchu Science Park, Baoshan Township, Hsinchu County 30075, Taiwan (R.O.C.)
Phone:	+886-3-5775586
Fax:	+886-3-5777868
Contact:	Hsiao-Wei Shen (ra@uniconvision.com.tw)

5.4 Identification of the Device:

Proprietary/Trade name:	UNICON Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens
Classification Product Code:	LPL, MVN
Regulation Number:	886.5925
Regulation Description:	Soft (hydrophilic) contact lens
Review Panel:	Ophthalmic
Device Class:	II

5.5 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

5.6 Indications for Use / Intended Use of the Device

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. When prescribed for daily disposable wear, the lens is to be discarded after each removal. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical disinfection system only.

5.7 Description of the Device

Unicon Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens is available as 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 composed of 2-hydroxyethyl methacrylate (HEMA) and 2,3-Dihydroxypropyl methacrylate (Glycerol methacrylate), which was cross-linked with Ethylene Glycol Dimethacrylate (EGDMA) via UV photo-polymerization. The Unicon Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens with visible tint is light tinted blue using C.I Reactive Blue 246 to make the lens more visible for handling. The lenses also contain a UV absorber {2-[3-(2H-Benzotriazol-2-yl)-4-hydroxyphenyl] ethyl methacrylate} which is included during the manufacturing process as an additive to block UV radiation. The average transmittance characteristics are less than 5% in the UVB range of 280 to 315 nm and less than 50% in the UVA range of 316 to 380 nm.

The properties of the lens are:

- Chord Diameter: 13.0 ~ 15.0 mm
- Base Curve: 8.0 ~ 10.0 mm
- Power: +6.00 ~ -12.00D
  (+4.50D ~ +6.00D in 0.50D per step;
  +4.00D ~ -6.00D in 0.25D per step;

	-6.50D ~ -12.00D in 0.50D per step)
• Center Thickness:	0.080 ~ 0.250 mm (varies with power)
• Refractive Index:	1.404 (hydrated)
• Water Content:	59%
• Oxygen Permeability:	$25 \times 10^{-11}(cm^2/sec)$*(ml O_2/mL*mmHg)
• Spectral Transmittance:	95% ± 5%
• UV Transmittance	at 280~315 nm: Avg<5%
	at 316~380 nm: Avg<50%

5.8 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 11737-1, ISO 11737-2, ISO 11138-3, ISO 17665-1, ASTM F2338, USP <71>, ISO 11987, ISO 18369-1, ISO 18369-2, ISO 18369-3, and ISO 18369-4 requirements.

- Biocompatibility

  Test results demonstrated that subject device complies with ISO 10993-1, ANSI/AAMI/ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-2, and ANSI/AAMI/ISO 10993-12 requirements.

- Performance
  - Water Content
  - Transmittance
  - Refractive Index
  - Oxygen Permeability
  - Mechanical Properties of Materials
  - Extractables
  - pH Value

- Osmolarity
- Geometric Parameters
- Specific Gravity
- Lens Compatibility with Multi-Purpose Solution

Test results demonstrated that subject device complies with ISO 18369-2, ANSI Z80.20, ISO 18369-3, ISO 18369-4, ASTM D882, and ASTM D1708 requirements.

5.9 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.

5.10 Substantial Equivalence Determination

The UNICON 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). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	Subject device	Predicate device	Substantial Equivalence Discussion
Manufacturer	UNICON Optical Co., LTD.	Interojo, Inc.	
Trade Name	UNICON Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens	Clalen 58 (hioxifilcon A) Soft (hydrophilic) Contact Lens for Daily Wear	
510(k) No.	(to be assigned)	K153766	
Indications For Use	The Unicon Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens is indicated for the correction of ametropia (myopia and	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	***Equivalent*** The main indication is the same, and the few different wordings do not affect the equivalence.

	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. When prescribed for daily disposable wear, the lens is to be discarded after each removal. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical disinfection system only.	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. Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients. 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	Substantial Equivalence Discussion
Manufacturer	UNICON Optical Co., LTD.	Interojo, Inc.	
Trade Name	UNICON Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens	Clalen 58 (hioxifilcon A) Soft (hydrophilic) Contact Lens For Daily Wear	
510(k) No.	(to be assigned)	K153766	
Type of Use	Prescription Use	Prescription Use	***Same***
UV blocking	Yes	Yes	***Same***
Production Method	Cast-molded	Fully molded	***Same***
USAN Name	Hioxifilcon A	Hioxifilcon A	***Same***
Water Content	59 ± 2%	59 ± 2%	***Same***
Oxygen Permeability	25×10^{-11}(cm^2/sec)*(ml O_2/mL*mmHg)	20.76×10^{-11}(cm^2/sec) (mlO_2/ml x mm Hg)	***Equivalent*** Not significantly different and meets the requirement; therefore it would not affect the equivalence.
Refractive Index	1.404 (hydrated)	1.403 (hydrated)	***Equivalent*** Not significantly different and meets the requirement; therefore it would not affect the equivalence.

5.11 Similarity and Difference

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

different between these two 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 and the predicate device are insignificant and do not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate device in intended use, design and performance claims.

5.12 Conclusion

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