May 16, 2019

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

Re: K182734
Trade/Device Name: Unicon Hydrogel (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: April 15, 2019
Received: April 17, 2019

Dear Hsiao-Wei 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/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,

for Malvina B. Eydelman, M.D.
Director
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)*
K182734

Device Name
Unicon Hydrogel (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens

Indications for Use *(Describe)*
The Unicon Hydrogel (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00 D or less of astigmatism. Eye care professionals may prescribe the lenses for daily disposable wear. Lenses shall be discarded upon 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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"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: May 14, 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 (etafilcon A) Soft (Hydrophilic) Daily Disposable 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:	Tangible Hydrogel with Tangible Polymer (etafilcon A) ASPHERIC Soft (Hydrophilic) Daily Disposable Contact Lens
Manufacturer:	Tangible Science LLC
Classification Product Code:	LPL, MVN
Regulation number:	886.5925

Device Class: II

510(k) Number: K172692

5.6 Intended Use/ Indications for Use of the Device

The Unicon Hydrogel (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00 D or less of astigmatism. Eye care professionals may prescribe the lenses for daily disposable wear. Lenses shall be discarded upon removal.

5.7 Device Description

The Unicon Hydrogel (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens is available as aspherical lenses manufactured by cast-molding method. The model illuminated with high water content (58 %). The hydrogel lens' material is a random copolymer composed of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA), which was cross-linked with Trimethylolpropane trimethacrylate (TMPTMA) and Ethylene Glycol Dimethacrylate (EGDMA) via UV photo-polymerization.

The Unicon Hydrogel (etafilcon A) Soft (Hydrophilic) Daily Disposable 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 30% in the UVA range of 316 to 380 nm. With more specific explanation, the “Unicon Hydrogel (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens” is 58% water and 42% HEMA/MAA cast-molding aspherical soft contact lens. It is blister packaged and produced from +4.00D to -6.00D in 0.25D per step, from +4.50D to +6.00D in 0.50D per step, and from

-6.50D to -13.00D in 0.50D per step.

The properties of the lenses are:

● Base Curve (mm):	7.85 to 10.0
● Chord Diameter (mm):	12.00 to 15.00
● Center Thickness (mm):	Varies with power 0.080 mm at -3.00D 0.200 mm at +3.00D
● Power (D):	+6.00 to -13.00
● Refractive Index (hydrated):	1.400 ±0.005
● Water Content (%):	58±2%
● Oxygen Permeability: ($x10^{-11}$ (cm^2/sec)(mlO_2/ml-mmHg))	21±20%
● Visible Light Transmittance (%):	95±5%
● UV Transmittance (%):	At 280~315 nm: Avg<5% At 316~380 nm: Avg<30%

5.8 Non-clinical Testing

A series of non-clinical studies were completed on this product. The 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.

The following tests were conducted on "Unicon Hydrogel (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens":

- **Sterilization test**
  Test results performed in test reports of sterilization test demonstrated that subject device complies with ISO 17665-1:2006, ISO 11737-1:2018, ISO 11737-2:2009, and ISO 11138-3:2017 requirements.

- **Shelf life test**

  Test results performed in test reports of shelf life test demonstrated that subject device complies with ISO 11987:2012 (E), ISO 18369-1:2006, ISO 18369-2:2012, ISO 18369-3:2017, ISO 18369-4:2017, ISO 17665-1:2006, and USP 32 – NF27 <71> requirements.

- **Biocompatibility tests**
  - *In Vitro* Cytotoxicity
  - White Rabbit Ocular Irritation
  - Acute Systemic Toxicity

  Tests were conducted in accordance with ISO 10993-1:2009, ISO 10993-2:2006, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-11:2017, and ISO 10993-12:2012 requirements.

- **Performance tests**
  - Humectant
  - Water Content
  - Transmittance
  - Refractive Index
  - Oxygen Permeability
  - Mechanical Properties of Materials
  - Extractables of Material Pigment
  - Extractables
  - pH Value
  - Osmolarity
  - Geometric Parameters
  - Specific Gravity

  Tests were conducted in accordance with ISO 18369-2:2012, ISO 18369-3:2017, ISO 18369-4:2017, ANSI Z80.20-2004, ASTM D882:2002, and ASTM D1708-13 requirements.

5.9 Clinical Testing

The safety and effectiveness of finished contact lenses manufactured from the etafilcon A have been established through previous clinical performance testing. And the pre-clinical testing results are sufficient in establishing substantial equivalence.

5.10 Substantial Equivalence Determination

The Unicon Hydrogel (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens submitted in this 510(k) file is substantially equivalent in intended use, main materials, design, safety and performance claims to the Tangible Hydrogel with Tangible Polymer (etafilcon A) ASPHERIC Soft (Hydrophilic) Daily Disposable Contact Lens (K172692). Differences between the devices cited in this section do not raise any new issues of substantial equivalence.

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary Name	Unicon Hydrogel (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens	Tangible Hydrogel with Tangible Polymer (etafilcon A) ASPHERIC Soft (Hydrophilic) Daily Disposable Contact Lens	N/A
510(k) No.	K182734	K172692	
Intended Use	The Unicon Hydrogel (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes	The Tangible Hydrogel with Tangible Polymer (etafilcon A) ASPHERIC Soft (Hydrophilic) Daily Disposable Contact Lens is indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic	Same

Item	Subject device	Predicate device	Substantial equivalence determination
	who may have 1.00 D or less of astigmatism. Eye care professionals may prescribe the lenses for daily disposable wear. Lenses shall be discarded upon removal.	persons with non-diseased eyes who may have 1.00 D or less of astigmatism. Eye care professionals may prescribe the lenses for daily disposable wear. Lenses shall be discarded upon removal.	
Type of use	Prescription Use	Prescription Use	Same
Single Use	Yes	Yes	Same
UV Blocking	Yes	Yes	Same
Production Method	Cast-Molded	Cast-Molded	Same
USAN Name	etafilcon A	etafilcon A	Same
Color additive	RB246 1,4-Bis[4-(2-methacryloxyethyl)phenylamino] anthraquinone copolymers	[Phthalocyaninato(2-)]copper	Different but RB246 is also approved; therefore it would not affect the equivalence
Base Curve	7.85 mm to 10.0 mm	7.85 mm to 10.0 mm	Same
Chord Diameter	12.0 mm to 15.00 mm	12.0 mm to 15.00 mm	Same
Center Thickness	Varies with power 0.080 mm at -3.00D 0.200 mm at +3.00D	0.01 mm to 0.20 mm	Different but the specification meets the requirement; therefore it would not affect the equivalence
Water Content (%)	58%	58%	Same
Refractive Index (hydrated)	1.400	1.400	Same

Item	Subject device	Predicate device	Substantial equivalence determination
Oxygen Permeability	23.42 × 10^{-11} (cm^2/sec) (ml O_2/ml-mmHg)	29.96 × 10^{-11} (cm^2/sec) (ml O_2/ml-mmHg)	Different but the specification meets the requirement; therefore it would not affect the equivalence
Power Range	+4.50D ~ +6.00D in 0.50D per step +4.00D ~ -6.00D in 0.25D per step -6.50D ~ -13.00D in 0.50D per step	+6.00D to -10.00D (in 0.25D steps) • Cylinder: -0.75D to -2.50D (in 0.25D steps) • Axis: 10° to 180° (in 10° steps) • Add: +1.00D to +2.50D (in 0.50D steps)	Different but it would not affect the equivalence
Visible Light Transmittance	95±5%	>98%	Different but the specification meets the requirement; therefore it would not affect the equivalence
UV transmittance	at 280~315 nm: Avg<5% at 316~380 nm: Avg<30%	at 280~315 nm: Avg<5% at 316~380 nm: Avg<30%	Same

5.11 Similarity and Difference

The Unicon Hydrogel (etafilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens has been compared with "Tangible Hydrogel with Tangible Polymer (etafilcon A) ASPHERIC Soft (Hydrophilic) Daily Disposable Contact Lens". The subject device has same intended use, principle of operation and similar

technological characteristics as the predicate device. Although there are some specifications that are different between two devices, the performance test has been completed to demonstrate that the differences between these parameters would not impact the safety and effectiveness of the subject device. The subject device has undergone safety and performance tests, and the results complied with the test requests. Therefore, the difference between the subject device and the predicate device did not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate device in intended use, safety and performance claims.

5.12 Conclusion

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