January 18, 2022

Unicon Optical Co., Ltd.
% Bret Andre
Principal Consultant
EyeReg Consulting, Inc.
6119 Canter Lane
West Linn, OR 97068

Re: K213216
Trade/Device Name: Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: December 6, 2021
Received: December 9, 2021

Dear Bret Andre:

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)*

K213216

Device Name

Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens

Indications for Use *(Describe)*

The Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens is indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and 1.00 diopter (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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510 (k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K213216

I. SUBMITTER

Date Prepared: September 24th, 2021

Name: **UNICON OPTICAL CO., LTD.**
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Consultant: Bret Andre
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6119 Canter Ln.
West Linn, OR 97068
Phone number: (503) 372-5226

II. DEVICE

Trade Name: **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens**

Common Name: Contact Lens, Daily Wear

Classification Name: Soft (hydrophilic) Contact Lens (21 CFR 886.5925)

Regulatory Class: Class II

Product Codes: LPL; MVN

Purpose of 510(k) Submission:

~ New Device ~

III. PREDICATE DEVICE

The **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens** is substantially equivalent to the following predicate device(s):

- "**ACUVUE® VITA™ (senofilcon C) Brand (Soft) Contact Lens"**
  By Johnson & Johnson Vision Care, Inc.
  510(k) number; **K160212**
  Primary Predicate

IV. DEVICE DESCRIPTION

The **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens** is a hemispherical shell with a molded spherical base curve and a molded front surface. The hydrophilic characteristics allow aqueous solutions to enter the lens. The lenses are fabricated from linofilcon A, which is a random co-polymer of silicone containing monomers and hydrophilic monomers. The lens consists of 62.0% linofilcon A and 38.0% water by weight when immersed in saline solution. The linofilcon A name has been adopted by the United States Adopted Names Council (USAN).

The **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens** contains C.I. Reactive Blue No. 19 (21 CFR Part 73.3127) for visibility and handling. The **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens** incorporates a benzotriazole UV blocking monomer to help protect against transmission of harmful UV radiation. The lens blocks >95% in the UVB range (280nm - 315nm), and >70% in the UVA range (316nm - 380nm).

The **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens** is manufactured in a spherical design configuration. The material properties and available parameters of the finished lenses are as follows:

Parameter	Range	Tolerance
Chord Diameter	13.00 mm to 15.00 mm	±0.20 mm
Center Thickness	0.080 mm @ -3.00 D	When ≤ 0.10 mm → ±0.010 mm + 10% When > 0.10 mm → ±0.015 mm + 5%
Base Curve	8.00 mm to 9.50 mm	±0.20 mm
Back Vertex Power (F'v)	+20.00D to -20.00D	When 0.00 < |F'v| ≤ 10.00 D → ±0.25 D When 10.00 < |F'v| ≤ 20.00 D → ±0.50 D
Surface Appearance	-	Lenses should be clear with no surface defect
Oxygen Permeability (x 10^{-11}(cm^2/sec)(mlO2)/(ml x mmHg))	100	±20%
Light Transmittance - Tinted (@ 380-780nm)	95%	±5%
Ultraviolet Radiation Transmittance	< 5 % T_{UVB} < 30 % T_{UVA}	$T_{UVB\ (280\ to\ 315\ nm)}$ < 0.05T_V $T_{UVA\ (316\ to\ 380\ nm)}$ < 0.50T_V
Water Content	38%	±2%
Refractive Index	1.415 (hydrated)	±0.005

V. INDICATIONS FOR USE

The **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens** is indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and 1.00 diopter (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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens** is substantially equivalent to the primary predicate device identified (K160212) regarding the following features:

- FDA category - Group V
- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Intended use – daily wear contact lenses
- Actions
- Indications for use
- Design configurations available (spherical)
- Cast molded production method
- Injection molded polypropylene blister packaging

The following matrix illustrates the production method, lens function and material characteristics of the **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens**, as well as the predicate device.

	Unicon Qualis (Subject Device)	**Johnson & Johnson Vision Care Acuvue Vita (K160212)**
Intended Use	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens
Actions	In its hydrated state, the contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina	In its hydrated state, the contact lens, when placed on the cornea, acts as a refracting medium to focus light rays on the retina
FDA Classification	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
FDA Group	FDA Group V	FDA Group V
Production Method	Fully molded	Fully molded
USAN name	linofilcon A	senofilcon C
Water Content (%)	38±2%	41±2%
Oxygen Permeability $\times 10^{-11}$ $(cm^2/sec)(mlO_2)/(ml \times mmHg @ 35°C))$ (revised Fatt method)	100 (edge-corrected)	103 (edge-corrected)
Refractive Index (hydrated)	1.415	1.420
UV Blocker	Yes - benzotriazole	Yes - benzotriazole
Manufacturing	Cast-Molded	Cast-Molded
Color	Blue Handling Tint C.I. Reactive Blue No. 19	Blue Handling Tint Reactive Blue Dye #4

The following matrix compares the indications for use of the **Qualis (Linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens** with the predicate device.

	Indications for Use
Unicon Qualis (Subject Device)	The **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens** is indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes and 1.00 diopter (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.
Johnson & Johnson Vision Care Acuvue Vita (K160212)	ACUVUE® (senofilcon C) Soft (hydrophilic) Contact Lens (spherical) is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 1.00D or less of astigmatism. ACUVUE® (senofilcon C) Soft (hydrophilic) Contact Lens – TORIC is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may have 10.00D or less of astigmatism. ACUVUE® (senofilcon C) Soft (hydrophilic) Contact Lens – MULTIFOCAL is indicated for daily wear for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00D of ADD power and may have 0.75D or less of astigmatism. ACUVUE® (senofilcon C) Soft (hydrophilic) Contact Lens – MULTIFOCAL-TORIC is indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and/or astigmatism) and presbyopia in phakic or aphakic persons with non-diseased eyes who may need up to 4.00D of ADD power and may have 10.00D or less of astigmatism. These lenses contain a UV Blocker to help protect against transmission of harmful UV radiation to the cornea and into the eye. Eye Care Professionals may prescribe the lenses either for daily disposable wear or frequent/planned replacement wear with cleaning, disinfection and scheduled replacement. When prescribed for daily disposable wear, lenses should be discarded upon removal. When prescribed for frequent/planned replacement wear, the lenses may be disinfected using a chemical disinfection system only. The contact lens is to be discarded after the recommended wearing period as prescribed by the Eye Care Professional.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Performance Testing

A series of non-clinical performance tests were performed to demonstrate the safety and effectiveness of the **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens**. The results support the claim that the **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens** is substantially equivalent to the currently marketed predicate device. A summary of the results from the non-clinical studies is presented below.

Toxicology:

All biocompatibility/toxicology tests were conducted in accordance with the GLP regulation.

- In-Vitro Cytotoxicity: Cytotoxicity testing was performed in accordance with ISO 10993-5 with results indicating that the finished lenses and packaging materials are non-toxic.
- Systemic Toxicity: The finished lenses and packaging materials meet the requirements of the systemic injection test in accordance with ISO 10993-11 and are considered non-toxic.
- Acute Ocular Irritation: Acute ocular irritation testing was performed in accordance with ISO 10993-10, and the extracts from finished lenses and packaging materials produced no ocular irritation.
- Skin Sensitization Study (Maximization Test): The skin sensitization study was conducted on the finished lenses in accordance with ISO 10993-10, and the contact lens extracts did not produce skin sensitization.
- 22-Day Ocular Irritation: The 22-day ocular irritation test was conducted in accordance with ISO 9394 on the finished lenses, and the contact lens extracts produced no ocular irritation.

Shelf Life:

Testing was performed to evaluate the stability, sterility, and package integrity of the **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens** over the duration of the labeled expiration date. The data presented supports establishment of the proposed shelf life.

Solution Compatibility

The physical compatibility of **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lenses** with commonly available cleaning and disinfection solutions (peroxide and MPDS) was confirmed following the methodology described in ISO 11981:2017, Ophthalmic optics - Contact lenses and contact lens care products - Determination of physical compatibility of contact lens care products with contact lenses.

Preservative Uptake and Release

Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lenses were analyzed for uptake and release of preservatives found in lens care products. Testing was conducted according to ISO 11986:2017, Ophthalmic optics - Contact lenses and contact lens care products - Determination of preservative uptake and release. Uptake and release profiles of linofilcon A contact lenses for polyaminopropyl biguanide (PAPB) and Polyquaternium-1 (PQ-1) demonstrate sub-detection limit amounts of release at each time point evaluated.

Performance Testing - Bench:

The following bench tests were completed: refractive index, water content, Dk, % transmission (visible & UV), tensile strength, modulus, % elongation to break, specific gravity and quantification of polymerization residuals. Results of physicochemical and mechanical property testing demonstrate consistent material properties between the **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens** and the predicate device.

Clinical Testing

An open-label, multi-center, randomized concurrent-control study with 91-day treatment follow-up was completed. Seventy-five (75) subjects were enrolled in the study—of which 50 subjects wore the test lenses (Qualis (linofilcon A) Silicone Hydrogel Soft Contact Lens for Daily Wear) and 25 subjects wore the control lenses (Acuvue Vita (senofilcon C) Monthly Contact Lens). Seventy-three (73) of the 75 enrolled subjects completed the study. No serious adverse events were reported. The study results establish substantially equivalent clinical performance between the test (Qualis) and control (Acuve Vita) lenses with respect to biomicroscopy findings, symptoms and vision safety measures; therefore, this clinical investigation supports the claim of substantial equivalence between the two lens types with regard to clinical safety and effectiveness.

VIII. CONCLUSIONS

Validity of Scientific Data

Laboratories under Good Laboratory Practice regulations conducted toxicology, microbiology, and shelf-life stability studies following scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7.

Substantial Equivalence

Information presented in this Premarket Notification establishes that the **Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens** is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the proposed indication.

Risks and Benefits

The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) daily wear contact lenses. The benefits to the patient are the same as those for other soft (hydrophilic) daily wear contact lenses.