



July 12, 2024

Unicon Optical Co., Ltd.
Bret Andre
Principal Consultant
Andre Vision and Device Research
6119 Canter Lane
West Linn, OR 97068

Re: K241707

Trade/Device Name: OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™;
OCuSOFT AMENITY™ Toric (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™;
OCuSOFT AMENITY™ Multifocal (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™

Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: May 21, 2024
Received: June 13, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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

Indications for Use

510(k) Number (if known)
K241707

Device Name

OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™;
OCuSOFT AMENITY™ Toric (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™;
OCuSOFT AMENITY™ Multifocal (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™

Indications for Use (Describe)

OCuSOFT® AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™ 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 people who exhibit astigmatism of 1.00 diopters or less that does not interfere with visual acuity.

OCuSOFT® AMENITY™ (linofilcon A) TORIC DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™ 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 -2.25 diopters.

OCuSOFT® AMENITY™ (linofilcon A) MULTIFOCAL DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™ are indicated for the correction of refractive ametropia (myopia and hyperopia) and 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 people who exhibit astigmatism of 1.00 diopters or less that does not interfere with visual acuity.

OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™ are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

SPECIAL 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: **K241707**

I. SUBMITTER

Date Prepared: July 1, 2024

Name: **UNICON OPTICAL CO., LTD.**
 Address: No.16, Gongye E. 9th Rd.
 Hsinchu Science Park, Baoshan Township
 Hsinchu County Hsinchu – District,
 TAIWAN 30075

Contact Person: Nick Liao
 Director

Phone number: +886-4-23551233

Consultant: Bret Andre
 EyeReg Consulting, Inc.
 6119 Canter Ln.
 West Linn, OR 97068

Phone number: (503) 372-5226

II. DEVICE

Trade Name: **OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™;**
OCuSOFT AMENITY™ Toric (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™;
OCuSOFT AMENITY™ Multifocal (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™

Common Name: Contact Lens, Daily Wear (Disposable)

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

Regulatory Class: Class II

Product Code: LPL; MVN

III. PREDICATE DEVICE

The **OCuSOFT AMENITY™ (linofilcon A) CONTACT LENSES with HYDRASEAL™** are substantially equivalent to the following predicate device(s):

- **“Qualis (linofilcon A) Soft (Hydrophilic) Daily Wear Contact Lens”**
By Unicon Optical Co., Ltd.
510(k) number; **K213216**
Primary Predicate
- **“Unicon Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens”**
By Unicon Optical Co., Ltd.
510(k) number; **K191929**
Reference Predicate
- **“Innova Vision Hydrogel (Hioxifilcon A) Soft (Hydrophilic) Contact Lens”**
By Innova Vision Inc.
510(k) number; **K213119**
Reference Predicate

IV. DEVICE DESCRIPTION

The **OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™** are a hemispherical shells with molded base curves and molded front surfaces. The hydrophilic characteristics allow aqueous solutions to enter the lenses. 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 with added lubricants. The linofilcon A name has been adopted by the United States Adopted Names Council (USAN).

The **OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™** contain C.I. Reactive Blue No. 19 (21 CFR Part 73.3127) for visibility and handling.

The **OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™** incorporate a benzotriazole UV blocking monomer to help protect against transmission of harmful UV radiation. The lenses block >95% in the UVB range (280nm - 315nm), and >70% in the UVA range (316nm - 380nm).

The following table lists the material properties and available parameters for the **OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™**:

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
Cylinder Power (F'c)	-0.25 D to -2.25 D (in 0.25 D steps)	When 0.00 < F'c ≤ 2.00 D → ±0.25 D When 2.00 < F'c ≤ 4.00 D → ±0.37 D
Cylinder Axis	5° to 180° in 5° steps	When 0.00 < F'c ≤ 1.50 D → ± 8° When F'c > 1.50 D → ± 5°
Multifocal Power	+0.25 D to +4.00 D (in 0.25 D steps)	±0.25D
Surface Appearance	-	Lenses should be clear with no surface defect
Oxygen Permeability (x 10 ⁻¹¹ (cm ² /sec)(mlO ₂)/(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

*ANSI Z80.20, Ophthalmics – Contact Lenses – Standard Terminology, Tolerances, Measurements and Physicochemical Properties (2016)

V. INDICATIONS FOR USE

OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™ 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 1.00 diopters or less that does not interfere with visual acuity.

OCuSOFT AMENITY™ **Toric** (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™ 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 -2.25 diopters.

OCuSOFT AMENITY™ **Multifocal** (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™ are indicated for the correction of refractive ametropia (myopia and hyperopia) and 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 1.00 diopters or less that does not interfere with visual acuity.

OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™ are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™** is substantially equivalent to the primary predicate device identified (K213216) regarding the following features:

- FDA category - Group V
- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Contact lens USAN material (linofilcon A)
- Intended use – daily wear contact lenses
- Actions
- Indications for use (single vision)
- Same manufacturing facility and cast molded production method
- Injection molded polypropylene blister packaging

The **OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™** is substantially equivalent to the reference predicate device identified (K191929) regarding the following features:

- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Intended use – daily wear contact lenses
- Actions
- Indications for use (single vision, toric)
- Same manufacturing facility and cast molded production method
- Injection molded polypropylene blister packaging
- Packaging solution composition

The **OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™** is substantially equivalent to the reference predicate device identified (K213119) regarding the following features:

- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Intended use – daily wear contact lenses
- Actions
- Indications for use (single vision, toric, multifocal)
- Same manufacturing production method (cast molded)
- Injection molded polypropylene blister packaging

The following matrix illustrates the production method, lens function and material characteristics of the **OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™**, as well as the predicate devices.

	OCuSOFT AMENITY™ (Subject Device)	Unicon Qualis (K213216)	Unicon Hydrogel (K191929)	Innova Vision Inc. Innova Vision Hydrogel (K213119)
Intended Use	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens	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	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)	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
FDA Group	FDA Group V	FDA Group V	FDA Group II	FDA Group II
Production Method	Fully molded	Fully molded	Fully molded	Fully molded
USAN name	linofilcon A	linofilcon A	hioxifilcon A	hioxifilcon A
Water Content (%)	38±2%	38±2%	59±2%	59±2%
Oxygen Permeability <small>x 10⁻¹¹ (cm²/sec)(mlO₂)/(ml x mmHg @ 35°C) (revised Fatt method)</small>	100 (edge-corrected)	100 (edge-corrected)	25	25
Refractive Index (hydrated)	1.415	1.415	1.404	1.400
UV Blocker	Yes - benzotriazole	Yes - benzotriazole	Yes - benzotriazole	Yes - benzotriazole
Manufacturing	Cast-Molded	Cast-Molded	Cast-Molded	Cast-Molded
Color	Blue Handling Tint C.I. Reactive Blue No. 19	Blue Handling Tint C.I. Reactive Blue No. 19	Blue Handling Tint Reactive Blue Dye #4	Blue Handling Tint C.I. Reactive Blue No. 19

The following matrix compares the indications for use of the **OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™** with the predicate device.

	Indications for Use
OCuSOFT AMENITY™ (Subject Device)	<p>OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™ 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 1.00 diopters or less that does not interfere with visual acuity.</p> <p>OCuSOFT AMENITY™ Toric (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™ 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 -2.25 diopters.</p> <p>OCuSOFT AMENITY™ Multifocal (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™ are indicated for the correction of refractive ametropia (myopia and hyperopia) and 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 1.00 diopters or less that does not interfere with visual acuity.</p> <p>OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™ are to be prescribed for single use, daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.</p>
Unicon Qualis (K213216)	<p>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.</p> <p>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.</p>
Unicon Hydrogel (K191929)	<p>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.</p> <p>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.</p>
Innova Vision Inc. Innova Vision Hydrogel (K213119)	<p>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.</p> <p>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.</p> <p>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</p>

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.

VII. PERFORMANCE DATA

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

Non-Clinical Performance Testing

Non-clinical performance tests were performed to demonstrate the safety and effectiveness of the linofilcon A finished contact lenses in K213216. Additional testing performed on the **OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™** include:

Toxicology:

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

- In-Vitro Cytotoxicity: Cytotoxicity testing was performed on extracts of the finished contact lenses and the contact lens storage solution in accordance with ISO 10993-5 with results indicating that the contact lens extracts and packaging solution is non-cytotoxic.
- Systemic Toxicity: Acute systemic toxicity was performed on the extracts of the finished contact lenses in accordance with ISO 10993-11 and no acute systemic toxicity was found.
- Acute Ocular Irritation: Acute ocular irritation testing was performed on extracts of the finished contact lens and the contact lens storage solution in accordance with ISO 10993-23 and resulted in no ocular irritation.

Shelf Life:

Testing was performed to evaluate the stability, sterility, and package integrity of the **OCuSOFT AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™** over the duration of the labeled expiration date. The data presented supports establishment of the proposed shelf life.

Bench Testing - Manufacturing Verification Testing:

Manufacturing verification testing was conducted to demonstrate the ability of our facility to manufacture lenses in the available design configurations to a variety of prescribed parameters on a repeatable basis. All lenses were manufactured to pre-determined finished product specifications within the ANSI Z80.20 tolerance.

Clinical Testing

A clinical study was performed to demonstrate the safety and effectiveness of the linofilcon A finished contact lenses in K213216.

VIII. CONCLUSIONS

Validity of Scientific Data

Pursuant to Good Laboratory Practice regulations, laboratories conducted non-clinical 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 **AMENITY™ (linofilcon A) DAILY DISPOSABLE CONTACT LENSES with HYDRASEAL™** 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.