



April 29, 2026

Geo Medical Co., Ltd.
% Bret Andre
Principal Consultant
Andre Vision and Device Research
6119 Canter Lane
West Linn, OR 97068

Re: K253885

Trade/Device Name: PUSCON WATER BALANCE-1DAY TINT (omafilcon A) SOFT
(HYDROPHILIC) CONTACT LENS; PUSCON WATER BALANCE-1DAY
COLOR (omafilcon A) SOFT (HYDROPHILIC) CONTACT LENSES

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (Hydrophilic) Contact Lens

Regulatory Class: Class II

Product Code: LPL, MVN

Dated: December 1, 2025

Received: March 30, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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

Indications for Use

Submission Number (if known)

K253885

Device Name

PUSCON WATER BALANCE-1DAY TINT (omafilcon A) SOFT (HYDROPHILIC) CONTACT LENS;
PUSCON WATER BALANCE-1DAY COLOR (omafilcon A) SOFT (HYDROPHILIC) CONTACT
LENSES

Indications for Use (Describe)

The Puscon Water Balance-1Day Tint (omafilcon A) Soft (Hydrophilic) Contact Lens and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for single use for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia. The lenses may be worn by people who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity. The lenses are available tinted and may be used to enhance or alter the apparent color of the eye. The lenses are 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.

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510 (k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K253885

I. SUBMITTER

Date Prepared: December 1, 2025

Name: **GEO MEDICAL CO., LTD.**
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6119 Canter Ln.
West Linn, OR 97068

Phone number: (503) 372-5226

II. DEVICE

Trade Name: **PUSCON WATER BALANCE-1DAY TINT (omafilcon A) SOFT (HYDROPHILIC) CONTACT LENS;
PUSCON WATER BALANCE-1DAY COLOR (omafilcon A) SOFT (HYDROPHILIC) CONTACT LENSES;**

Common Name: Contact Lens, Daily Wear

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

Regulatory Class: Class II

Product Code: LPL; MVN

Purpose of 510(k) Submission:

~ New Device ~

III. PREDICATE DEVICE

The **Puscon Water Balance-1Day Tint and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses** are substantially equivalent to the following predicate device:

- **“Aveo (omafilcon A) Soft (Hydrophilic) Contact Lenses”**
By Supervision Optimax SDN BHD
Primary Predicate
510(k) number; **K180985**
- **“Innova Vision Hydrogel (Etafilcon A) Soft (Hydrophilic) Contact Lens”**
By Innova Vision Inc.
Reference Predicate
510(k) number; **K222954**
- **“Pegavision (etafilcon A) Color Daily Disposable Soft (hydrophilic) Contact Lenses, Pegavision (etafilcon A) Color Soft (hydrophilic) Contact Lenses”**
By Pegavision Corporation
Reference Predicate
510(k) number; **K200296**

IV. DEVICE DESCRIPTION

Puscon Water Balance-1Day Tint and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses for daily disposable wear are made from a material containing 59% water and 41% omafilcon A, consisting of 2-hydroxy-ethylmethacrylate and 2-methacryloyloxyethyl phos-phorycholine polymers cross-linked with ethyleneglycol dimethacrylate. The hydrophilic characteristics allow aqueous solutions to enter the lens. The omafilcon A name has been adopted by the United States Adopted Names Council (USAN).

The **Puscon Water Balance-1Day Tint (omafilcon A) Soft (Hydrophilic) Contact Lens** is tinted for visibility with C.I. Reactive Blue 69. **Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses** contain a unique tinted pattern to enhance or alter the apparent color of the eye. The color lenses are processed to incorporate the ‘listed’ color additives and contain only the amount of the additive needed to accomplish the intended coloring effect. The color lenses contain one or a combination of one or more of the following ‘listed’ color additives:

| Name of Colorant | Listing |
|----------------------|-----------------|
| Titanium Dioxide | 21 CFR 73.3126 |
| Pigment Green 7 | 21 CFR 73.3124 |
| C.I. Pigment Blue 36 | 21 CFR 73.3110a |
| Pigment Violet 23 | 21 CFR 73.3107 |
| Vat Orange 1 | 21 CFR 73.3112 |
| Vat Brown 1 | 21 CFR 73.3117 |
| Chromium (III) Oxide | 21 CFR 73.3111 |
| C.I. Pigment Red 101 | 21 CFR 73.3125 |
| Mica | 21 CFR 73.3128 |

When producing the color lenses, the manufacturing process changes the specifications of the clear lens by pad-printing the color pigments—entrapping the colorants in the interpenetrating network of the contact lens material—in a location that corresponds to the iris. The color pigments used are not removed by lens handling and cleaning/disinfecting procedures. Except for affecting the amount of light transmittance through the lens, the coloring process does not alter the original characteristics of the pre-tinted lens.

The **Puscon Water Balance-1Day Tint and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses** incorporate a benzotriazole UV absorbing monomer (2-[3-(2H-Benzotriazol-2-yl)-4-hydroxyphenyl]ethyl methacrylate) to help protect against transmission of harmful UV radiation. The lens blocks >95% in the UVB range (280nm - 315nm), and >50% in the UVA range (316nm - 380nm).

The **Puscon Water Balance-1Day Tint and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses** are manufactured in a spherical design configuration. The material properties and available parameters of the finished lenses are as follows:

| Parameter | Range | Tolerance* |
|--|--|---|
| Chord Diameter | 12.00 mm to 18.00 mm | ±0.20 mm |
| Center Thickness | 0.080 mm to 0.140 mm | When ≤ 0.10 mm → ±0.010 mm + 10% When > 0.10 mm → ±0.015 mm + 5% |
| Base Curve | 7.0 mm to 10.0 mm | ±0.20 mm |
| Back Vertex Power (F'v) | 0.00 D to -6.00D (in 0.25D steps) -6.00D to -10.00 D (in 0.50D steps) | When $0.00 < F'v \leq 10.00$ D → ±0.25 D |
| Surface Appearance | - | Lenses should be clear with no surface defect |
| Oxygen Permeability (x 10⁻¹¹(cm²/sec)(mlO₂)/(ml x mmHg)) | 27 | ±20% |
| Light Transmission (@ 380-780nm) | 95% | ±5% |
| Water Content | 59% | ±2% |
| Refractive Index | 1.400 (hydrated) | ±0.005 |

* ISO 18369-2:2017 Ophthalmic optics — Contact lenses — Part 2: Tolerances

V. INDICATIONS FOR USE

The **Puscon Water Balance-1Day Tint (omafilcon A) Soft (Hydrophilic) Contact Lens** and **Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses** are indicated for single use for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia. The lenses may be worn by people who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity. The lenses are available tinted and may be used to enhance or alter the apparent color of the eye. The lenses are to be discarded after each removal.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **Puscon Water Balance-1Day Tint and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses** are comparable to the primary predicate device specified (K180985) in the following aspects:

- USAN contact lens material (omafilcon A)
- FDA Group 2 (>50% H₂O, non-ionic polymer)
- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Intended use – daily disposable contact lenses
- Actions
- Indications for use (single vision)
- Cast molded production method
- Sterilization method – steam sterilization (moist heat)

The **Puscon Water Balance-1Day Tint and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses** are comparable to the reference predicate device specified (K222954) in the following aspects:

- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Intended use – daily disposable contact lenses
- Actions
- Indications for use (single vision)
- Cast molded production method
- Ultraviolet light absorber
- Sterilization method – steam sterilization (moist heat)

The **Puscon Water Balance-1Day Tint and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses** are comparable to the reference predicate device specified (K200296) in the following aspects:

- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Intended use – daily disposable contact lenses
- Actions
- Indications for use (single vision)
- Cast molded production method
- Pad-printing contact lens tinting method (for color lenses)
- Sterilization method – steam sterilization (moist heat)

The following matrix illustrates the classification, production method, lens function and material characteristics of the **Puscon Water Balance-1Day Tint and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses**, as well as the predicate devices.

| | GEO MEDICAL CO., LTD. Puscon Water Balance-1Day Tint and Color (Subject Device) | Supervision Optimax SDN BHD Aveo (Predicate Device) (K180985) | Innova Vision Inc. Innova Vision Hydrogel (Reference Predicate K222954) | Pegavision Corporation Pegavision Color (Reference Predicate K200296) |
|---|---|---|---|---|
| Actions | The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina | The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina | The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina | The contact lenses act as a refractive medium that focus light rays from near and distant objects 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 2 (>50% H ₂ O, non-ionic polymer) | FDA Group 2 (>50% H ₂ O, non-ionic polymer) | FDA Group 4 (>50% H ₂ O, ionic polymer) | FDA Group 4 (>50% H ₂ O, ionic polymer) |
| Product Code | LPL; MVN | LPL; MVN | LPL; MVN | LPL; MVN |
| Production Method | Fully molded | Fully molded | Fully molded | Fully molded |
| Sterilization Method | Steam sterilization (moist heat) | Steam sterilization (moist heat) | Steam sterilization (moist heat) | Steam sterilization (moist heat) |
| USAN name | omafilcon A | omafilcon A | etafilcon A | etafilcon A |
| Water Content (%) | 59 ± 2% | 59 ± 2% | 58 ± 2% | 58±2% |
| Oxygen Permeability x 10 ⁻¹¹ (cm ² /sec)(mlO ₂)/(ml x mmHg @ 35°C) ^a | 27 ± 20% | 25.68 ± 20% | 24 ± 20% | 19.73 ± 20% |
| Refractive Index (hydrated) | 1.400 ± 0.005 | 1.4002 ± 0.005 | 1.400 ± 0.005 | 1.402 ± 0.005 |
| UV Blocker | Yes | Yes | Yes (same as the subject device) | No |
| Pad-Printed Tinting | Yes | No | No | Yes (same method as subject device) |
| Color Additives | C.I. Reactive Blue 69 (visibility tinting) Titanium Dioxide Pigment Green 7 C.I. Pigment Blue 36 Pigment Violet 23 Vat Orange 1 Vat Brown 1 Chromium (III) Oxide C.I. Pigment Red 101 Mica | Reactive Blue Dye 246 | C.I. reactive blue 19 | FDA listed colorants** |

^a (Polarographic method, edge corrected)

** Not disclosed

The following table compares the indications for use of the **Puscon Water Balance-1Day Tint and Puscon Water Balance-1Day Color (Omafilcon A) Soft (Hydrophilic) Contact Lenses** with the predicate devices.

| | Indications for Use |
|--|--|
| GEO MEDICAL CO., LTD. Puscon Water Balance-1Day Tint and Color (Subject Device) | <p>The Puscon Water Balance-1Day Tint (omafilcon A) Soft (Hydrophilic) Contact Lens and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses are indicated for single use for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia. The lenses may be worn by people who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity. The lenses are available tinted and may be used to enhance or alter the apparent color of the eye. The lenses are to be discarded after each removal.</p> |
| Supervision Optimax SDN BHD Aveo (Predicate Device) (K180985) | <p>Aveo (omafilcon A) Aspheric Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of visual acuity in not aphakic persons with non-diseased eyes that are myopic or hyperopic and exhibit astigmatism of 1.00D or less that does not interfere with visual acuity.</p> <p>Aveo (omafilcon A) Toric Soft (Hydrophilic) Contact Lenses are indicated the daily wear for the correction of visual acuity in not aphakic persons with non-diseased eyes that are myopic or hyperopic and exhibit astigmatism of between 0.50D and 2.50D or less that does not interfere with visual acuity.</p> <p>Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.</p> <p><u>Frequent Planned Replacement Wear:</u> When prescribed for frequent planned replacement wear the lenses are to be cleaned, rinsed and disinfected each time they are removed from the patients' eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lenses may be disinfected using a chemical disinfection system.</p> <p><u>Disposable Wear:</u> When prescribed for Daily Disposable Wear the lens is to be discarded after each removal.</p> |
| Innova Vision Inc. Innova Vision Hydrogel (Reference Predicate K222954) | <p>Sphere/Asphere Innova Vision Sphere and Asphere (Etafilcon 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 (Etafilcon 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 (Etafilcon 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.</p> <p>Multifocal Toric Innova Vision Multifocal Toric (Etafilcon 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.</p> <p>Eye Care Practitioners may prescribe the Innova Vision Hydrogel (Etafilcon A) Soft (Hydrophilic) Contact lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement or for single-use disposable wear.</p> |

| | |
|---|--|
| | <p>When prescribed for frequent/planned replacement, the Innova Vision Hydrogel (Etafilcon 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 (Etafilcon A) Soft (Hydrophilic) Contact Lens is to be discarded after each removal.</p> |
| <p>Pegavision Corporation Pegavision Color (Reference Predicate K200296)</p> | <p>Pegavision (Etafilcon A) Color SPHERE and ASPHERE Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +6.00 to -12.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.</p> <p>Toric Pegavision (Etafilcon A) Color Toric Daily Disposable Soft (Hydrophilic) Contact Page 3 Lenses are indicated for daily wear for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +6.00 to -12.00 diopters and astigmatic corrections from -0.25 to -3.50 diopters. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.</p> <p>Multifocal Pegavision (Etafilcon A) Color Multifocal Daily Disposable Soft (Hydrophilic) Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and/or non-aphakic persons with non-diseased eyes in powers from +6.50 to -12.25 diopters and with non-diseased eyes that may require a reading addition from +0.25 to +3.00 diopters. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity. The lens is available tinted and may be used to enhance or alter the apparent color of the eye.</p> <p>Pegavision (Etafilcon A) Color Daily Disposable Soft (Hydrophilic) Contact Lenses are intended for single-use disposable wear.</p> |

VII.

PERFORMANCE DATA

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

Non-clinical Testing

A series of non-clinical testing was performed to demonstrate the safety and effectiveness of the **Puscon Water Balance-1Day Tint and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses**. The results support the claim that **Puscon Water Balance-1Day Tint and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses** are substantially equivalent to the currently marketed predicate device. A summary of the results from the non-clinical studies is presented below.

Toxicology:

All non-clinical 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, blister package materials, and primary packaging solution are not cytotoxic.
- Systemic Toxicity: Acute systemic injection testing was performed in accordance with ISO 10993-11 with results indicating that the extracts from finished lenses and blister package materials do not produce acute systemic toxicity.
- Acute Ocular Irritation: Acute ocular irritation testing was performed in accordance with ISO 10993-23 with results indicating that the primary packaging solution and extracts from finished lenses and blister package materials produced no ocular irritation.
- Sensitization: Maximization sensitization testing was performed in accordance with ISO 10993-10 with results indicating that the primary packaging solution is non-sensitizing.

Shelf Life:

Testing was conducted to assess the stability and package integrity of **Puscon Water Balance-1Day Tint and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses** over their labeled expiration date. The stability study samples are subjected to real time (25°C) and accelerated (45°C) aging and evaluated at predefined time intervals for shape and appearance, package integrity (ASTM F1929-23), seal strength (ASTM F88), physical and geometric stability (ISO 18369-3), material properties (ISO 18369-4), pH and osmolality of the primary packaging solution, and sterility. The data indicated that all evaluated parameters remained within the established specifications for the finished device.

Sterility:

The initial sterility of the **Puscon Water Balance-1Day Tint and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses** was confirmed using the direct method following ISO 11737-2. Bacteriostasis and fungistasis (B/F) testing was conducted to validate the sterility test method by ensuring the lens does not inhibit the

detection of microorganisms during sterility testing.

Physicochemical & Mechanical Properties:

The following tests were completed to confirm substantial equivalence with the predicate device: refractive index, water content, Dk, % transmission (visible & UV), tensile strength, modulus, % elongation to break, specific gravity and polymerization residuals. Results of physicochemical and mechanical property testing demonstrate consistent material properties between the **Puscon Water Balance-1Day Tint and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses** and the predicate device.

The results of the non-clinical testing on the subject device demonstrate that: the lens material and extracts are non-toxic and non-irritating, the lens specifications are stable for the duration of the labeled expiration date, and lens physical and material properties are consistent with currently marketed lenses.

Clinical Testing

Clinical testing is not required for this application.

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 **Puscon Water Balance-1Day Tint and Puscon Water Balance-1Day Color (omafilcon A) Soft (Hydrophilic) Contact Lenses** are as safe and effective as the predicate devices 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.