



April 17, 2024

Innova Vision Inc.  
% Bret Andre  
Principal Consultant  
Andre Vision and Device Research  
6119 Canter Lane  
West Linn, OR 97068

Re: K240519

Trade/Device Name: Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft  
Contact Lens

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (Hydrophilic) Contact Lens

Regulatory Class: Class II

Product Code: LPL, MVN

Dated: January 31, 2024

Received: February 23, 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](mailto: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

Submission Number (if known)

K240519

Device Name

Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens

Indications for Use (Describe)

### Sphere/Asphere:

Innova Vision Sphere and Asphere (inifilcon A) Silicone Hydrogel 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.

### Toric:

Innova Vision Toric (inifilcon A) Silicone Hydrogel 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 -2.25 diopters.

### Multifocal:

Innova Vision Multifocal (inifilcon A) Silicone Hydrogel 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.

### Multifocal Toric:

Innova Vision Multifocal Toric (inifilcon A) Silicone Hydrogel 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 -2.25 diopters.

Eye Care Practitioners may prescribe the Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft 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 (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft 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 (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens is 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)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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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:** K240519

### **I. SUBMITTER**

Date Prepared: January 29<sup>th</sup> 2024

Name: **INNOVA VISION, INC.**

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Hsinchu Science Park 300091,  
Hsinchu, Taiwan

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

Phone number: (503) 372-5226

### **II. DEVICE**

Trade Name: **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft 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:**

~ Device Change ~

### III. PREDICATE DEVICE

The **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens** is substantially equivalent to the following predicate devices:

- **“Innova Vision (inifilcon A) Silicone Hydrogel Soft (Hydrophilic) Contact Lens”**  
By Innova Vision, Inc.  
510(k) number; **K232139**  
Primary Predicate
- **“Innova Vision Hydrogel (Etafilcon A) Soft (Hydrophilic) Contact Lens”**  
By Innova Vision, Inc.  
510(k) number; **K222954**  
Primary Predicate
- **“Total30, Total30 for Astigmatism, Total30 Multifocal, Total30 Multifocal Toric, Total30 Asphere”**  
By Alcon Laboratories Inc.  
510(k) number; **K210436**  
Reference Predicate

### IV. DEVICE DESCRIPTION

The **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft 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 inifilcon A, which is a random co-polymer of silicone containing monomers and hydrophilic monomers. The lens consists of 60.0% inifilcon A and 40.0% water by weight when immersed in saline solution. The inifilcon A name has been adopted by the United States Adopted Names Council (USAN).

The **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens** contains C.I. Reactive Blue 247 (21 CFR Part 73.3100 ) for visibility and handling. The **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft 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 >50% in the UVA range (315nm - 380nm). The **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens** is manufactured in sphere/asphere, toric, multifocal and multifocal-toric design configurations. 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        | 0.050 mm to 0.580 mm                      | When ≤ 0.10 mm → ±0.010 mm + 10%<br>When > 0.10 mm → ±0.015 mm + 5%                       |
| Base Curve              | 8.0 mm to 9.8 mm                          | ±0.20 mm                                                                                  |
| Back Vertex Power (F'v) | -20.00 D to +20.00 D<br>(in 0.25 D steps) | When $0.00 <  F'v  \leq 10.00$ D → ±0.25 D<br>When $10.00 <  F'v  \leq 20.00$ D → ±0.50 D |
| Cylinder Power (F'c)    | -0.25 D to -2.25 D<br>(in 0.25 D steps)   | When $0.00 <  F'c  \leq 2.00$ D → ±0.25 D<br>When $2.00 <  F'c  \leq 4.00$ D → ±0.37 D    |

|                                                                                                                                 |                                                   |                                                                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| Cylinder Axis                                                                                                                   | 10° to 180° in 10° steps<br>(in 10° steps)        | When $0.00 <  F'c  \leq 1.50 \text{ D} \rightarrow \pm 8^\circ$<br>When $ F'c  > 1.50 \text{ D} \rightarrow \pm 5^\circ$                       |
| Multifocal Power                                                                                                                | +0.25 D to +4.00 D<br>(in 0.25 D steps)           | $\pm 0.25 \text{ D}$                                                                                                                           |
| Oxygen Permeability<br>( $\times 10^{-11} (\text{cm}^2 \cdot \text{ml O}_2) / (\text{sec} \cdot \text{ml} \cdot \text{mmHg})$ ) | 100                                               | $\pm 20\%$                                                                                                                                     |
| Visible Light Transmittance                                                                                                     | $> 95\%$                                          | $\pm 5\%$                                                                                                                                      |
| Ultraviolet radiation Transmittance                                                                                             | $< 5\% T_{\text{UVB}}$<br>$< 50\% T_{\text{UVA}}$ | $T_{\text{UVB}} (280 \text{ to } 315 \text{ nm}) < 0.05 T_{\text{V}}$<br>$T_{\text{UVA}} (315 \text{ to } 380 \text{ nm}) < 0.05 T_{\text{V}}$ |
| Water Content                                                                                                                   | 40%                                               | $\pm 2\%$                                                                                                                                      |
| Refractive Index                                                                                                                | 1.410                                             | $\pm 0.005$                                                                                                                                    |

## V. INDICATIONS FOR USE

### Sphere/Asphere:

Innova Vision Sphere and Asphere (inifilcon A) Silicone Hydrogel 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.

### Toric:

Innova Vision Toric (inifilcon A) Silicone Hydrogel 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 -2.25 diopters.

### Multifocal:

Innova Vision Multifocal (inifilcon A) Silicone Hydrogel 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.

### Multifocal Toric:

Innova Vision Multifocal Toric (inifilcon A) Silicone Hydrogel 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 -2.25 diopters.

Eye Care Practitioners may prescribe the Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft 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 (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft 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 (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens is to be discarded after each removal.

## **VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE**

The **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens** is substantially equivalent to the primary predicate device identified (K232139) regarding the following features:

- FDA category - Group V
- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- USAN Material (inifilcon A)
- Intended use – daily wear contact lenses
- Actions
- Indications for use (same lens design configurations)
- Benzotriazole UV absorbing monomer (same monomer)
- Cast molded production method (same manufacturing facility and quality controls)
- Injection molded polypropylene blister packaging (same packaging)

The **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens** is substantially equivalent to the reference predicate device identified (K222954) regarding the following features:

- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Intended use – daily wear contact lenses
- Indications for use
- Cast molded production method (same manufacturing facility and quality controls)
- Injection molded polypropylene blister packaging (same packaging and storage solution)
- Buffer solution (same formulation)

The **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens** is substantially equivalent to the reference predicate device identified (K210436) regarding the following features:

- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Intended use – daily wear contact lenses
- Indications for use
- Cast molded production method
- Handling tint (Reactive Blue 247)

The following matrix illustrates the production method, lens function and material characteristics of the **Innova Vision (inifilcon A) Silicone Hydrogel Soft (Hydrophilic) Contact Lens**, as well as the predicate devices.

|                                                                                                                                     | <b>Innova Vision Silicone Hydrogel<br/>By Innova Vision Inc.<br/>(Subject Device)</b>                                             | <b>Innova Vision Silicone Hydrogel<br/>By Innova Vision Inc.<br/>(K232139)</b>                                                    | <b>Innova Vision Hydrogel<br/>By Innova Vision Inc.<br/>(K222954)</b>                                                             | <b>TOTAL30 by Alcon<br/>Laboratories, Inc.<br/>(K210436)</b>                                                                      |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| <b>Intended Use</b>                                                                                                                 | Daily wear,<br>Soft (hydrophilic) contact lens                                                                                    | Daily wear,<br>Soft (hydrophilic) contact lens                                                                                    | Daily wear,<br>Soft (hydrophilic) contact lens                                                                                    | Daily wear,<br>Soft (hydrophilic) contact lens                                                                                    |
| <b>Actions</b>                                                                                                                      | 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 |
| <b>FDA Classification</b>                                                                                                           | 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)                                                                                 |
| <b>FDA Classification Product Code(s)</b>                                                                                           | LPL; MVN                                                                                                                          | LPL; MVN                                                                                                                          | LPL; MVN                                                                                                                          | LPL; MVN                                                                                                                          |
| <b>FDA Group</b>                                                                                                                    | FDA Group V                                                                                                                       | FDA Group V                                                                                                                       | FDA Group II                                                                                                                      | FDA Group V                                                                                                                       |
| <b>USAN name</b>                                                                                                                    | inifilcon A                                                                                                                       | inifilcon A                                                                                                                       | etafilcon A                                                                                                                       | lehfilcon A                                                                                                                       |
| <b>Water Content (%)</b>                                                                                                            | 40±2%                                                                                                                             | 40±2%                                                                                                                             | 58±2%                                                                                                                             | 55±2%                                                                                                                             |
| <b>Oxygen Permeability</b><br>$\times 10^{-11}$ (cm <sup>2</sup> /sec)(mlO <sub>2</sub> )/(ml x mmHg @ 35°C)) (revised Fatt method) | 100                                                                                                                               | 100                                                                                                                               | 24                                                                                                                                | 123                                                                                                                               |
| <b>Refractive Index (hydrated)</b>                                                                                                  | 1.410                                                                                                                             | 1.410                                                                                                                             | 1.400                                                                                                                             | 1.40                                                                                                                              |
| <b>UV Blocker</b>                                                                                                                   | Yes - benzotriazole                                                                                                               | Yes - benzotriazole                                                                                                               | Yes - benzotriazole                                                                                                               | Yes – two benzotriazole monomers                                                                                                  |
| <b>Manufacturing</b>                                                                                                                | Cast-Molded (Heat Curing)                                                                                                         | Cast-Molded (UV Curing)                                                                                                           | Cast-Molded (UV Curing)                                                                                                           | Cast-Molded                                                                                                                       |
| <b>Color</b>                                                                                                                        | Blue Handling Tint<br>Reactive Blue 247                                                                                           | Blue Handling Tint<br>C.I. Reactive Blue No. 19                                                                                   | Blue Handling Tint<br>C.I. Reactive Blue No. 19                                                                                   | Blue Handling Tint<br>Reactive Blue 247                                                                                           |
| <b>Buffer Contains H2O2</b>                                                                                                         | Yes                                                                                                                               | No                                                                                                                                | Yes                                                                                                                               | No                                                                                                                                |

The following matrix compares the indications for use of the **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens** with the predicate device.

|                                                                               | Indications for Use                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Innova Vision Silicone Hydrogel By Innova Vision Inc. (Subject Device)</b> | <p><b>Sphere/Asphere:</b><br/>Innova Vision Sphere and Asphere (inifilcon A) Silicone Hydrogel 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><b>Toric:</b><br/>Innova Vision Toric (inifilcon A) Silicone Hydrogel 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 -2.25 diopters.</p> <p><b>Multifocal:</b><br/>Innova Vision Multifocal (inifilcon A) Silicone Hydrogel 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><b>Multifocal Toric:</b><br/>Innova Vision Multifocal Toric (inifilcon A) Silicone Hydrogel 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 correction from -0.25 to -2.25 diopters.</p> <p>Eye Care Practitioners may prescribe the Innova Vision (inifilcon A) Silicone Hydrogel 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 (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft 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.</p> <p>When prescribed for single-use disposable wear, Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens is to be discarded after each removal.</p> |
| <b>Innova Vision Silicone Hydrogel By Innova Vision Inc. (K232139)</b>        | Same as the subject device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

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|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Innova<br/>Vision<br/>Hydrogel<br/>By Innova<br/>Vision Inc.<br/>(K222954)</b> | <p>Same as the subject device</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>TOTAL30 by<br/>Alcon<br/>Laboratories,<br/>Inc.<br/>(K210436)</b>              | <p>TOTAL30 (lehfilcon A) spherical soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.</p> <p>TOTAL30 Asphere (lehfilcon A) soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes with up to approximately 1.50 diopters (D) of astigmatism that does not interfere with visual acuity.</p> <p>TOTAL30 for Astigmatism (lehfilcon A) toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with nondiseased eyes with up to 6.00 diopters (D) of astigmatism.</p> <p>TOTAL30 Multifocal (lehfilcon A) soft contact lenses are indicated for the optical correction of presbyopia with or without refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.</p> <p>TOTAL30 Multifocal Toric (lehfilcon A) soft contact lenses are indicated for the optical correction of presbyopia with or without refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes who may require a reading addition of +3.00 diopters (D) or less and who may have up to 6.00 diopters (D) of astigmatism.</p> <p>The lenses are to be prescribed for daily wear with removal for cleaning and disinfection (chemical not heat) prior to reinsertion, or disposal, as recommended by the eye care professional. Lenses should be discarded and replaced with a new pair each month, or more often, if recommended by the eye care professional.</p> |

## 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 **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens**. The results support the claim that the **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens** is substantially equivalent to the currently marketed predicate devices. Refer below to a summary of the results from the non-clinical studies.

#### *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 are not cytotoxic.
- Systemic Toxicity: The finished lenses meet the requirements of the systemic injection test in accordance with ISO 10993-11 and do not produce acute systemic toxicity.
- Acute Ocular Irritation: Acute ocular irritation testing was performed in accordance with ISO 10993-10, and the extracts from finished lenses produced no ocular irritation.

The **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens** uses the same blister packaging materials and packaging solution as the predicate devices. Biocompatibility testing for the packaging materials and solution was addressed in previously submitted biocompatibility assessments.

#### *Shelf Life:*

Testing was performed to evaluate the stability, sterility, and package integrity of the **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft 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 **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens** with commonly available cleaning and disinfection solutions (peroxide and MPDS) was confirmed.

#### *Preservative Uptake and Release*

**Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lenses** were analyzed for uptake and release of preservatives found in lens care products. Preservative uptake and release testing is referenced in K232139.

### *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 **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens** and the predicate device.

### Clinical Testing

Clinical performance testing for the **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft Contact Lens** was addressed by the predicate device.

## **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 **Innova Vision (inifilcon A) Silicone Hydrogel (Hydrophilic) Daily Wear Soft 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.