



December 17, 2024

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

Re: K242413

Trade/Device Name: VizionFocus (mifilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lens; VizionFocus Color (mifilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lens

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (Hydrophilic) Contact Lens

Regulatory Class: Class II

Product Code: LPL, MVN

Dated: August 8, 2024

Received: November 19, 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/pmnmn.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.

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

Enclosure

Indications for Use

Submission Number (if known)

K242413

Device Name

VizionFocus (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lens;
VizionFocus Color (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lens

Indications for Use (Describe)

Sphere/Asphere:

The VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Daily Disposable Soft (hydrophilic) Contact Lenses in the spherical/aspheric design 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.

Toric:

The VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Daily Disposable Soft (hydrophilic) Contact Lenses in the toric design 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:

The VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Daily Disposable Soft (hydrophilic) Contact Lenses in the multifocal design 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.

The VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Daily Disposable Soft (hydrophilic) Contact Lenses 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. The VizionFocus Color (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses are tinted to enhance or alter the apparent color of the eye.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510 (k) SUMMARY

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

The assigned 510(k) number is: K242413

I. SUBMITTER

Date Prepared: November 14, 2024

Name: **VIZIONFOCUS INC.**
Address: No.66, Youyi Rd., Zhunan Township,
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 6119 Canter Ln.
 West Linn, OR 97068
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II. DEVICE

Trade Name: **VizionFocus (mifilcon A) Silicone Hydrogel Soft (hydrophilic) Daily
Disposable Contact Lens;
VizionFocus Color (mifilcon A) Silicone Hydrogel Soft (hydrophilic) Daily
Disposable Contact Lens;**

Common
Name: lens, contact, (disposable)

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

Regulatory
Class: Class II

Product Codes: MVN

Purpose of 510(k) Submission:

~ New Device ~

III. PREDICATE DEVICE

The **VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses** are substantially equivalent to the following predicate devices:

- **“Clariti 1 day (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens”**
By CooperVision, Inc.
510(k) number; **K181920**
Product Code: MVN; LPL
Primary Predicate
- **“AIR OPTIX plus HydraGlyde, AIR OPTIX plus HydraGlyde for Astigmatism, AIR OPTIX plus HydraGlyde Multifocal, AIR OPTIX plus HydraGlyde Multifocal Toric”**
By Alcon Laboratories, Inc.
510(k) number; **K160609**
Product Code: LPL
Reference Predicate
- **“DAILIES (NELFILCON A) ONE-DAY SOFT CONTACT LENS”**
By CIBA VISION CORPORATION
510(k) number; **K963487**
Product Code: LPL
Reference Predicate
- **ILICON (ocufilcon D) Soft (Hydrophilic) Daily Wear Contact Lenses (Tinted, Color)”**
By Vizionfocus, Inc.
510(k) number; **K182247**
Product Code: MVN; LPL
Reference Predicate

IV. DEVICE DESCRIPTION

The **VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses** are 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 mififilcon A, which is a random co-polymer of silicone containing monomers and hydrophilic monomers. The lenses consist of 40.0% mififilcon A and 60.0% water by weight when immersed in saline solution. The mififilcon A name has been adopted by the United States Adopted Names Council (USAN).

The **VizionFocus (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lens** contains phthalocyanine blue (21 CFR Part 74.3045) for visibility and handling. The **VizionFocus Color (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses** are tinted to enhance or alter the apparent color of the eye. The 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 lenses contain one or a combination of one or more of the following ‘listed’ color additives:

Color Additive	Listing
Rutile TiO ₂	21 CFR § 73.3126
Iron Oxide	21 CFR § 73.3125
(Phthalocyaninato(2-))Copper	21 CFR § 74.3045
Carbazole Violet	21 CFR § 73.3107
Phthalocyanine Green	21 CFR § 73.3124
Mica	21 CFR § 73.3128

When producing the color lenses, the manufacturing process changes the specifications to the clear contact lens by pad-printing the color pigment(s)—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 tinting pattern has a clear pupil diameter of 6.0 mm.

The **VizionFocus and VizionFocus Color (mifilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses** 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 >80% in the UVA range (316nm - 380nm). The **VizionFocus and VizionFocus Color (mifilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses** are manufactured in spherical/aspheric, toric, and multifocal design configurations. The material properties and available parameters of the finished lenses are as follows:

Parameter	Range	Tolerance
Chord Diameter	11.00 mm to 15.00 mm	±0.20 mm
Center Thickness	0.050 mm to 0.150 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)	-20.00 D to +20.00 D (in 0.25 D steps)	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	10° to 180° in 10° steps (in 10° 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
Oxygen Permeability ($\times 10^{-11}$ (cm ² •ml O ₂)/(sec•ml•mmHg))	80	±20%
Visible Light Transmittance	>95%	±5%
Ultraviolet radiation Transmittance	< 5% T _{UVB} <20% T _{UVA}	T _{UVB} (280 to 315nm) < 0.05 T _V T _{UVA} (316 to 380nm) < 0.05 T _V
Water Content	60%	±2%
Refractive Index	1.395	±0.005

V. INDICATIONS FOR USE

Sphere/Asphere:

The VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Daily Disposable Soft (hydrophilic) Contact Lenses in the spherical/aspheric design 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.

Toric:

The VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Daily Disposable Soft (hydrophilic) Contact Lenses in the toric design 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:

The VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Daily Disposable Soft (hydrophilic) Contact Lenses in the multifocal design 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.

The VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Daily Disposable Soft (hydrophilic) Contact Lenses 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. The VizionFocus Color (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses are tinted to enhance or alter the apparent color of the eye.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses** are substantially equivalent to the primary predicate device identified (K181920) with regards to the following features:

- FDA category - Group V
- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Intended use – daily disposable contact lenses
- Indications for use
- Cast molded production method
- Injection molded blister packaging

The **VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses** are substantially equivalent to the reference predicate devices identified (K160609 & K963487) with regards to the following features:

- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Intended use – daily wear contact lenses
- Indications for use
- Buffer solution (contains common ingredients with subject device buffer solution)

The **VizionFocus and VizionFocus Color (mifilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses** are substantially equivalent to the reference predicate device identified (K182247) with regards to the following features:

- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Intended use – daily wear contact lenses
- 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)
- Handling tint and color additives (same colorants and production process)
- Pad-printing color lens manufacturing process (same facility pad-printing process)

The following matrix illustrates the production method, lens function and material characteristics of the **VizionFocus and VizionFocus Color (mifilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses**, as well as the predicate devices.

	VizionFocus and VizionFocus Color Silicone Hydrogel By VizionFocus Inc. (Subject Device)	Clariti 1 day By CooperVision Inc. (K181920)	AIR OPTIX plus HydraGlyde By Alcon Laboratories, Inc. (K160609)	Dailies One-Day By Ciba Vision Corporation (K963487)	ILICON By Vizionfocus, Inc. (K182247)
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	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	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)	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
Product Code(s)	MVN	LPL; MVN	LPL	MVN	LPL; MVN
FDA Group	FDA Group V	FDA Group V	FDA Group V	FDA Group II	FDA Group IV
USAN name	mifilcon A	somofilcon A	lotrafilcon B	nelfilcon A	ocufilcon D
Water Content (%)	60±2%	56±2%	33±2%	69±2%	55±2%
Oxygen Permeability x 10 ⁻¹¹ (cm ² /sec)(mlO ₂)/(ml x mmHg @ 35°C))	80	60	110	26	19.6
Refractive Index (wet)	1.395	1.4003	1.42	1.38	1.410
UV Blocker	Yes - benzotriazole	Yes - benzophenone	None Reported	None Reported	Yes - benzotriazole
Manufacturing	Cast-Molded	Cast-Molded	Cast-Molded	Cast-Molded	Cast-Molded
Color	Rutile TiO ₂ Iron Oxide Phthalocyanine Blue Carbazole Violet Phthalocyanine Green Mica	None	Phthalocyanine Blue	None Reported	Rutile TiO ₂ Iron Oxide (Phthalocyanine(2-))Copper Carbazole Violet Phthalocyanine Green
Blister Packaging	Yes	Yes	Yes	Yes	Yes

The following matrix compares the indications for use of the **VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses** with the predicate devices.

	Indications for Use
<p>VizionFocus and VizionFocus Color Silicone Hydrogel By VizionFocus Inc. (Subject Device)</p>	<p>Sphere/Asphere: The VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Daily Disposable Soft (hydrophilic) Contact Lenses in the spherical/aspheric design 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>Toric: The VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Daily Disposable Soft (hydrophilic) Contact Lenses in the toric design 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>Multifocal: The VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Daily Disposable Soft (hydrophilic) Contact Lenses in the multifocal design 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>The VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Daily Disposable Soft (hydrophilic) Contact Lenses 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. The VizionFocus Color (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses are tinted to enhance or alter the apparent color of the eye.</p>
<p>Clariti 1 day By CooperVision Inc. (K181920)</p>	<p>The CLARITI 1 DAY (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity.</p> <p>The CLARITI 1 DAY TORIC (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters.</p> <p>The CLARITI 1 DAY MULTIFOCAL (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may require a reading addition of +3.00 Diopters or less and may exhibit astigmatism up to 1.50 Diopters or less.</p> <p>The CLARITI 1 DAY MULTIFOCAL TORIC (somofilcon A) Soft (hydrophilic) Daily Disposable Contact Lens with UV blocker is indicated for daily wear single use only for the optical correction of refractive ametropia (myopia and hyperopia) and/or presbyopia in phakic or aphakic persons with non-diseased eyes that may exhibit astigmatism up to 10.00 Diopters and require a reading addition of +3.00 Diopters or less.</p> <p>The Clariti 1 Day (somofilcon A) Soft (hydrophilic) Contact Lenses are indicated for daily wear single use only. The lenses are to be discarded upon removal; therefore, no cleaning or disinfection is required.</p>
<p>AIR OPTIX plus HydraGlyde By Alcon Laboratories,</p>	<p>Lotrafilcon B 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 and up to approximately 1.50 diopters of astigmatism that does not interfere with visual acuity.</p> <p>Lotrafilcon B toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with non-diseased eyes and up to 6.00 diopters (D) or less of astigmatism.</p>

<p>Inc. (K160609)</p>	<p>Lotrafilcon B multifocal 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.</p> <p>Lotrafilcon B multifocal toric soft contact lenses are indicated for the optical correction of refractive ametropia (myopia and hyperopia) and presbyopia in phakic or aphakic persons with non-diseased eyes and up to 6.00 diopters (D) or less of refractive and/or corneal astigmatism.</p> <p>Eye care professionals may prescribe the lenses for daily disposable wear (lenses are discarded upon removal from the eye) or daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion and frequent replacement, as recommended by the eye care professional.</p>
<p>Dailies One-Day By Ciba Vision Corporation (K963487)</p>	<p>DAILIES (nelfilcon A) ONE-DAY CONTACT LENSES are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia, and astigmatism) in non-aphakic persons with non-diseased eyes.</p> <p>DAILIES (nelfilcon A) ONE-DAY CONTACT LENSES are to be prescribed for single use Daily Disposable Wear. DAILIES lenses are not intended to be cleaned or disinfected and should be discarded after a single use.</p>
<p>ILICON By Vizionfocus, Inc. (K182247)</p>	<p>The ILICON (ocufilcon D) SPHERICAL contact lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased that may exhibit astigmatism up to 2.0 diopters that does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.</p> <p>The ILICON (ocufilcon D) TORIC Soft Contact Lenses for daily wear are indicated for the correction of refractive error in aphakic and not-aphakic persons with non-diseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 5.00 diopters. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.</p> <p>The ILICON (ocufilcon D) MULTIFOCAL Soft Contact Lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 2.0 diopters that does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.</p> <p>The ILICON (ocufilcon D) MULTIFOCAL TORIC Soft Contact Lenses for daily wear are indicated for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 5.0 diopters that does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.</p> <p>Daily wear replacement schedules may vary from patient to patient and should be decided by eye care practitioners in consultation with their patients.</p> <p>Eye care practitioners may prescribe any of the above lenses for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.</p> <p>Eye care practitioners may prescribe any of the above lenses for single use daily disposable wear. When prescribed for daily disposable wear the lens is to be discarded after each removal.</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 **VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses**. The results support the claim that the **VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses** are 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 and packaging solution 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 10993-23, and the packaging solution and extracts from finished lenses produced no ocular irritation.
- Skin Sensitization Study (Maximization Test): The skin sensitization study was conducted on the finished lenses in accordance with ISO 10993-10, and the contact lens extracts did not produce skin sensitization.
- 22-Day Ocular Irritation: The 22-day ocular irritation test was conducted in accordance with ISO 9394 on the finished lenses, and the contact lenses produced no ocular irritation.

The **VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses** use identical packaging materials as the predicate device cleared under K182247. Cytotoxicity, systemic toxicity, and acute ocular irritation studies for the final packaging materials are referenced in K182247.

Shelf Life:

Testing was performed to evaluate the stability, sterility, and package integrity of the **VizionFocus and VizionFocus Color (mififilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses** over the duration of the labeled expiration date. The data presented supports establishment of the proposed shelf life.

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 **VizionFocus and VizionFocus Color (mifilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses** and the predicate device.

Clinical Testing

A multi-center, single-masked (examiner), bilateral, randomized concurrent-control study with 91-day treatment follow-up was completed. One hundred twenty (120) subjects were enrolled in the study—of which 60 subjects wore the test lenses (VizionFocus Silicone Hydrogel Daily Disposable Contact Lens) and 60 subjects wore the control lenses (Clariti 1 day (somofilcon A) Soft (Hydrophilic) Daily Disposable Contact Lens). Of the 120 subjects enrolled, 117 subjects completed all scheduled visits (60 subjects in the test group and 57 subjects in the control group). There were 93 females and 26 males in the study (1:0.28 ratio female: male). The average age of the subjects was 26.35 years (25.85 years in the test group and 26.85 years in the control group). One (1) serious adverse event was reported in the control arm (presumed microbial keratitis), and no serious adverse events were reported in the test arm. The study results establish substantially equivalent clinical performance between the test (VizionFocus Silicone Hydrogel) and control (Clariti 1 day) lenses with respect to biomicroscopy findings, symptoms, adverse reactions and vision safety measures (i.e., keratometry changes, refractive changes, and best corrected visual acuity).

VIII. CONCLUSIONS

Validity of Scientific Data

Laboratories under Good Laboratory Practice regulations conducted toxicology, microbiology, and 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 **VizionFocus and VizionFocus Color (mifilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lenses** are 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.