September 10, 2025

Vizionfocus Inc.
Bret Andre
Principal Consultant
Eyereg Consulting Inc.
6119 Canter Lane
West Linn, OR 97068

Re: K251573
Trade/Device Name: VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: May 20, 2025
Received: August 5, 2025

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251573

Device Name

VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens

Indications for Use *(Describe)*

Sphere and Asphere:
The VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens in the spherical and aspheric design are indicated for monthly disposable wear 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 (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens in the toric design is indicated for monthly disposable wear 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 (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens in the multifocal design is indicated for monthly disposable wear 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 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.

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.

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: K251573

I. SUBMITTER

Date Prepared: July 18th , 2025

Name: **VIZIONFOCUS INC.**
Address: No.66, Youyi Rd., Zhunan Township,
Miaoli County 350,
Taiwan (R.O.C.)

Contact Person: Angus Shih
General Manager
Phone number: 037-582900

Consultant: Bret Andre
EyeReg Consulting, Inc.
6119 Canter Ln.
West Linn, OR 97068
Phone number: (503) 372-5226

II. DEVICE

Trade Name: **VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens**
Common Name: lenses, soft contact, daily wear

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

Regulatory Class: Class II

Product Codes: LPL

Purpose of 510(k) Submission:

~ New Device ~

III. PREDICATE DEVICE

The **VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens** is substantially equivalent to the following predicate devices:

- **"Sauflon Clariti (Somofilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker"**
  By Sauflon Pharmaceuticals, Ltd.
  510(k) number; **K130342**
  Product Code: LPL
  Primary Predicate
- **"VizionFocus (mifilcon A) Silicone Hydrogel Soft (hydrophilic) Daily Disposable Contact Lens"**
  By Vizionfocus, Inc.
  510(k) number; **K242413**
  Product Code: MVN; LPL
  Reference Predicate

IV. DEVICE DESCRIPTION

The **VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens** is a hemispherical shell with a molded base curve and a molded front surface. The hydrophilic characteristics allow aqueous solutions to enter the lens. The lens is fabricated from somofilcon A, which is a random co-polymer of silicone containing monomers and hydrophilic monomers. The lens consists of 44.0% somofilcon A and 56.0% water by weight when immersed in saline solution. The somofilcon A name has been adopted by the United States Adopted Names Council (USAN).

The **VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens** contains phthalocyanine blue (21 CFR Part 74.3045) for visibility and handling. The **VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) 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 >80% in the UVA range (316nm - 380nm).

The **VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens** is manufactured in spherical/aspheric, toric, 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 0.200 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 (x 10^{-11} (cm^2•ml O2)/(sec•ml•mmHg))	60	±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	56%	±2%
Refractive Index	1.398	±0.005

V. INDICATIONS FOR USE

Sphere and Asphere:
The **VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens** in the spherical and aspheric design are indicated for monthly disposable wear 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 (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens** in the toric design is indicated for monthly disposable wear 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 (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens** in the multifocal design is indicated for monthly disposable wear 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 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens** is substantially equivalent to the primary predicate device identified (K130342) with regards to the following features:

- FDA category - Group V
- FDA classification – Class II, Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- FDA product code – LPL
- Contact lens material (USAN) – somofilcon A
- Intended use – Frequent/planned replacement daily wear contact lenses
- Indications for use
- Cast molded production method
- Injection molded blister packaging

The **VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens** is substantially equivalent to the reference predicate device identified (K242413) with regards to the following features:

- FDA category - Group V
- FDA classification – Class II, Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Indications for use
- Lens designs (sphere/asphere, toric, multifocal)
- Benzotriazole UV absorbing monomer (same monomer)
- Cast molded production method (same manufacturing facility and quality controls)
- Injection molded polypropylene blister packaging (same packaging materials and processes)
- Handling tint and color additives (same colorant and production process)

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

	VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens By VizionFocus Inc. (Subject Device)	**Sauflon Clariti (somofilcon A) Soft (hydrophilic) Contact Lens with UV Blocker By Sauflon Pharmaceuticals, Ltd. (K130342)**	**VizionFocus (mifilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens By VizionFocus Inc. (K242413)**
Intended Use	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
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)
Product Code(s)	LPL; MVN	LPL; MVN	MVN
FDA Group	FDA Group V	FDA Group V	FDA Group V
USAN name	somofilcon A	somofilcon A	mifilcon A
Water Content (%)	56±2%	56±2%	60±2%
Oxygen Permeability $\times 10^{-11}$ $(cm^2/sec)(mlO_2)/(ml \times mmHg @ 35°C))$	60	60	80
Refractive Index (wet)	1.398	1.4003	1.395
UV Blocker	Yes - benzotriazole	Yes - benzophenone	Yes - benzotriazole
Manufacturing	Cast-Molded	Cast-Molded	Cast-Molded
Color	Phthalocyanine Blue	None	Rutile TiO2 Iron Oxide Phthalocyanine Blue Carbazole Violet Phthalocyanine Green Mica
Blister Packaging	Yes	Yes	Yes

The following matrix compares the indications for use of the **VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens** with the predicate devices.

	Indications for Use
VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens By VizionFocus Inc. (Subject Device)	Sphere and Asphere: The VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens in the spherical and aspheric design are indicated for monthly disposable wear 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 (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens in the toric design is indicated for monthly disposable wear 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 (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens in the multifocal design is indicated for monthly disposable wear 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 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.
Sauflon Clariti (somofilcon A) Soft (hydrophilic) Contact Lens with UV Blocker By SAUFLON PHARMACEUTICALS, LTD. (K130342)	Sauflon Clariti (somofilcon A) Soft (hiydrophilic) Contact Lens with UV blocker is indicated for: The SAUFLON CLARITI (somofilcon A) Soft (hydrophilic) Contact Lens with UV blocker is indicated for monthly disposable wear 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. The SAUFLON CLARITI TORIC (somofilcon A) Soft (hydrophilic) Contact Lens with UV blocker is indicated for monthly disposable wear for the optical correction of refractive ametropia (myopia and hyperopia) in phakic or aphakic persons with nondiseased eyes that may exhibit astigmatism up to 10.00 Diopters. The SAUFLON CLARITI MULTIFOCAL (somofilcon A) Soft (hydrophilic) Contact Lens with UV blocker is indicated for monthly disposable wear 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. The SAUFLON CLARITI MULTIFOCAL TORIC (somofilcon A) Soft (hydrophilic) Contact Lens with UV blocker is indicated for monthly disposable wear 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 that may require a reading addition of +3.00 Diopters or less. The lenses may be prescribed for daily wear with removal for cleaning and disinfection (chemical, not heat) prior to reinsertion as recommended by the eye care professional. Sauflon Clariti (somofilcon A) Soft (hydrophilic) Contact lens with UV blocker help protect against transmission of harmful UV radiation to the cornea and into the eye.
VizionFocus (mifilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens By VizionFocus Inc.	**Sphere/Asphere:** The VizionFocus and VizionFocus Color (mifilcon 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.

(K242413)	**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.

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 (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens**. The results support the claim that the **VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) 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 10993-23, and the extracts from finished lenses produced no ocular irritation.

The **VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens** uses identical packaging materials and primary packaging solution as the predicate device cleared under K242413. Cytotoxicity, systemic toxicity, and acute ocular irritation studies for the final packaging materials are referenced in K242413. Cytotoxicity and acute ocular irritation studies for the primary packaging solution are referenced in K242413.

Shelf Life:

Testing was performed to evaluate the stability, sterility, and package integrity of the **VizionFocus (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens** 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 (somofilcon A) Silicone Hydrogel Soft (hydrophilic) Contact Lens** and the primary predicate device.

Clinical Testing

Clinical testing is not required. The clinical performance of soft (hydrophilic) contact lenses manufactured from (somofilcon A) materials has been demonstrated previously.

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 (somofilcon A) Silicone Hydrogel Soft (hydrophilic) 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.