November 01, 2024

Acuity Polymers, Inc.
Chris Naivar
Regulatory Affairs
1667 Lake Ave.
Building 59, Suite 303
Rochester, NY 14615

Re: K242393
Trade/Device Name: Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid gas permeable contact lens
Regulatory Class: Class II
Product Code: HQD, MUW
Dated: August 8, 2024
Received: August 13, 2024

Dear Chris Naivar:

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)*

K242393

Device Name

Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses

Indications for Use *(Describe)*

The Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® SPHERICAL Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.

The Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® TORIC Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear 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 10.00 diopters.

The Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® MULTIFOCAL/BIFOCAL Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear 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 4.00 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® IRREGULAR CORNEA Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

The Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® ORTHOKERATOLOGY contact lenses are indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters with eyes having astigmatism up to 1.50 diopters in non-diseased eyes. To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

Furthermore, eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment and the saline bath provided by scleral lens designs.

Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® (tisilfocon A) SCLERAL lenses are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject:

I . cannot be adequately corrected with spectacle lenses
2. requires a rigid gas permeable contact lens surface to improve vision
3. is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities.

Common causes of corneal distortion include but are not limited to corneal infections, trauma,

tractions as a result of scar formation secondary to refractive surgery (e.g. LASIK or radial keratotomy) or corneal transplantation. Causes may also include corneal degeneration (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan's dystrophy).

The Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® (tisilfocon A) SCLERAL lenses are indicated for therapeutic use in eyes with ocular surface disease (e.g. ocular Graft-versus-Host disease, Sjogren's syndrome, dry eye syndrome and Filamentary Keratitis}, limbal stem cell deficiency (e.g. Stevens-Johnson syndrome, chemical radiation and thermal burns), disorders of the skin (e.g. atopy, ectodermal dysplasia), neurotrophic keratitis (e.g. Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g. anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® (tisilfocon A) (tisilfocon A) SCLERAL lenses may concurrently provide correction of refractive error.

Eyecare practitioners may prescribe the lenses or frequent/ planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

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: K242393

I. SUBMITTER

Date Prepared: November 1, 2024

Name: **Acuity Polymers, Inc.**
Address: 1667 Lake Ave
Building 59, Suite 303
Rochester, NY
14615

Contact Person: Chris Naivar
Regulatory Affairs
Phone number: (512) 203-3684

II. DEVICE

Trade Name: Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses

Common Name: Daily wear rigid gas permeable contact lens

Classification Name: Rigid gas permeable contact lens. (21 CFR 886.5916)

Regulatory Class: Class II

Product Code: HQD; MUW

III. PREDICATE DEVICE

The **Acuity 181™ (tisilfocon A)** and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG®** Rigid Gas Permeable Contact Lens is substantially equivalent to the following predicate devices:

- Hyper GP (tisilfocon A) Daily Wear Contact Lens, 510(k) K182304
- Visionary Optics Scleral Contact Lens (tisilfocon A), 510(k) K223394
- Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens; Acuity 100™ (hexafocon A) Rigid Gas Permeable Contact Lens; Acuity 200™ with Tangible® Hydra-PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens; Acuity 100™ with Tangible® Hydra-PEG® (hexafocon A) Rigid Gas Permeable Contact Lens, 510(k) K240618

IV. DEVICE DESCRIPTION

Acuity 181™ (tisilfocon A) Rigid Gas Permeable Contact Lens is manufactured from a machine latheable rigid gas permeable material composed of siloxanyl fluoromethacrylate copolymer that is tinted for visibility and available with or without an ultraviolet (UV) light absorber. The lenses may be plasma treated during the manufacturing process.

Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Contact Lenses are treated to incorporate Hydra-PEG® Technology (HPT), which is a thin polyethylene glycol (PEG)-based polymer that is covalently (permanently) bonded to the surface of the contact lens and is designed to enhance the surface properties of the contact lens while retaining the mechanical properties of the underlying material. When coated with **Tangible™ Hydra-PEG®**, the underlying material, tisilfocon A, is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (sessile drop contact angle compared to untreated lenses).

Acuity 181™ (tisilfocon A) and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG®** Rigid Gas Permeable Contact Lens are available in spherical, aspherical, toric, multifocal/bifocal, orthokeratology, and scleral design for daily wear only.

	Acuity 181™ (tisilfocon A)		
	Uncoated	Tangible™ Hydra-PEG® Coated	Plasma Treated
Average Sessile Drop Wetting Angle (degrees), n=30	95.4	48.8	19.2
Standard Deviation	3.89	3.64	6.45

The **Acuity 181™ (tisilfocon A)** and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG®** Rigid Gas Permeable Contact Lens may be packaged and shipped "dry" or "wet" in a polypropylene contact lens case (510(k) K171539). The primary container for shipping the **Acuity 181™ (tisilfocon A)** and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG®** Rigid Gas Permeable Contact Lens is the deep-well contact lens case (510(k) K171539). When shipped "wet," the **Acuity 181™ (tisilfocon A)** and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG®** Rigid Gas Permeable Contact Lens may be packaged and shipped in the Bausch & Lomb's Boston Simplus Multi-Action Solution (510(k) K181627).

The physical properties of the **Acuity 181™ (tisilfocon A)** and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG®** Rigid Gas Permeable Contact Lens is as follows:

USAN	Tisilfocon A
Refractive Index	1.434
Specific Gravity	1.22
Water Content	< 1.0%
Oxygen Permeability, Dk, ISO/Fatt Method 10^{-11} (cm^3 O_2 x cm/ (cm^2 x sec x mmHg)@ 35°C	181
Hardness, Shore D [±2 D]	81
Flex Modulus, MPa	1488
Maximum, Flexural Strength, MPa	55.6
Toughness, J/m^3	2.23
Visible Tints (Lenses contain one or more of the following color additives conforming to 21 CFR Part 73 & 74 Subpart D)	D&C Green No. 6, Solvent Yellow No. 18, D&C Violet No. 2, D&C Red No. 17
Wet Shipping Compatible Solution	Bausch & Lomb's Boston Simplus Multi-Action Solution
FDA Group	Group III, Fluoro Silicone Acrylate

	Acuity 181™ (tisilfocon A) Luminous Transmittance	
	Uncoated	Tangible™ Hydra-PEG® Coated
Light Transmission (380-780nm)	87.0%	87.4%
UVA Transmission (315- 380nm)	15.1%	17.1%
UVB Transmission (280-315nm)	0.033%	0.034%

Acuity 181™ (tisilfocon A) and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG®** are available in the following lens design parameters and tolerances:

Parameter	Range	Tolerance
Base Curve	4.00mm to 12.00mm	± 0.05mm ± 0.10mm (Scleral)
Center Thickness	.08mm to 3.00mm	± 0.02mm ± 0.10mm (Scleral)
Diameter	7.00mm to 26.00mm	± 0.10mm ± 0.25mm (Scleral)
Spherical Power	-35.00 D TO 35.00 D (in .12D steps)	± 0.12 (0 to </= 5D) ± 0.18 (5 to </= 10.0D) ± 0.25 (10 to </= 15D) ± 0.37 (15 to </= 20D) ± 0.50 (over 20D)
Cylindrical Power	+10.00 D TO -10.00 D (in .12 D steps)	± 0.25 (0 to </= 2D) ± 0.37 (2 to </= 4D) ± 0.50 (over 4D)
Cylindrical Axis	1° to 180° (in 1° steps)	± 5°
Bifocal Add	+12.00 D to 6.00 D (in 0.12 D steps)	± 0.25D
Multifocal Power	+1.00 D to 4.00 D (in .012 D steps)	± 0.25D

Acuity 181™ (tisilfocon A) and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG®** are hemispherical shells of the following dimensions:

SPHERICAL AND ASPHERIC LENS	
Power Range Diameter Base Curve Range	-35.00D to +35.00D in 0.25D increments 7.0mm to 26.0mm 4.00mm to 12.00 mm in 0.01mm increments
MULTIFOCAL/BIFOCAL LENS (CENTERED, DECENTERED, CRESCENT)	
Power Range Diameter Base Curve Range Segment Heights Add Powers Prism Ballast	-35.00D to +35.00D in 0.25D increments 7.0mm to 26.0mm 4.00mm to 12.00mm in 0.01mm increments -2.00mm to +1.00mm in 0.5 increments +1.00D to +4.00D in 0.25D increments 0.5 to 3.5 prism diopters in 0.5D increments
TORIC LENS	
Power Range Diameter Base Curve Range Toricity	-35.00D to +35.00D in 0.25D increments 7.0mm to 26.0mm 4.00mm to 12.00mm in 0.01mm increments Up to 10.00 Diopters
SCLERAL CONTACT LENS	
Power Range Diameter Normalized Vaults	-35.00D to +35.00D in 0.25D increments 16mm to 26.0mm 2.50mm to 6.00mm
ORTHOKERATOLOGY LENS	
Power Range Diameter Base Curve Range Reverse Curve Alignment Curve 1 Alignment Curve 2 Peripheral Curve	-5.00D to +1.50D in 0.25D 9.6mm to 11.6mm 7.30mm to 10.15mm 5.00mm to 9.00mm (Steeper than the base curve) 7.00mm to 9.0mm (Steeper than the base curve but flatter than the Reverse Curve 7.25mm to 9.25mm (Steeper than the base curve but flatter than the Alignment Curve 1 and Reserve Curve) 9.00mm to 15.00mm

V. INDICATIONS FOR USE

The **Acuity 181™ (tisilfocon A)** and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® SPHERICAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia.

The **Acuity 181™ (tisilfocon A)** and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® TORIC** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear 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 10.00 diopters.

The **Acuity 181™ (tisilfocon A)** and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® MULTIFOCAL/BIFOCAL** Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear 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 4.00 diopters and are presbyopic requiring add power of up to +4.00 diopters.

The **Acuity 181™ (tisilfocon A)** and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® IRREGULAR CORNEA** Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

The **Acuity 181™ (tisilfocon A)** and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® ORTHOKERATOLOGY** contact lenses are indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters with eyes having astigmatism up to 1.50 diopters in non-diseased eyes. To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

Furthermore, eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment and the saline bath provided by scleral lens designs.

Acuity 181™ (tisilfocon A) and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® (tisilfocon A)** SCLERAL lenses are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject:

l. cannot be adequately corrected with spectacle lenses
2. requires a rigid gas permeable contact lens surface to improve vision
3. is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities.

Common causes of corneal distortion include but are not limited to corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery (e.g., LASIK or radial keratotomy) or corneal transplantation. Causes may also include corneal degeneration (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan's dystrophy).

The Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® (tisilfocon A) SCLERAL lenses are indicated for therapeutic use in eyes with ocular surface disease (e.g. ocular Graft-versus-Host disease, Sjogren's syndrome, dry eye syndrome and Filamentary Keratitis}, limbal stem cell deficiency (e.g. Stevens-Johnson syndrome, chemical radiation and thermal burns), disorders of the skin (e.g. atopy, ectodermal dysplasia), neurotrophic keratitis (e.g. Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g. anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® (tisilfocon A) (tisilfocon A) SCLERAL lenses may concurrently provide correction of refractive error.

Eyecare practitioners may prescribe the lenses or frequent/ planned replacement wear, with cleaning, disinfection, and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses** is substantially equivalent to Hyper GP (tisilfocon A) Daily Wear Contact Lens (cleared under K182304) in terms of the following:

- Intended Use- Daily Wear
- Indication for Use
- USAN- contact lens material composition
- Contact Lens Design
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- May be surface coated with Tangible Hydra-PEG
- Product Method- Lathe Cut

The **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses** is substantially equivalent to Visionary Optics Scleral Contact Lens (tisilfocon A) cleared under K223394 in terms of the following:

- Intended Use- Daily Wear
- Indication for Use
- USAN- contact lens material composition
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- Product Method- Lathe Cut

The **Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses** is substantially equivalent to Acuity200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens; Acuity 100™ (hexafocon A) Rigid Gas Permeable Contact Lens; Acuity 200™ with Tangible® Hydra-PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens; Acuity 100™ with Tangible® Hydra-PEG® (hexafocon A) Rigid Gas Permeable Contact Lens cleared under K240618 in terms of the following:

- Intended Use- Daily Wear
- Indication for Use
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- May be surface coated with Tangible Hydra-PEG
- Product Method- Lathe Cut

Any differences in technological characteristics between the two devices do not raise any safety or effectiveness questions.

The following matrix illustrates the production method, intended use, indication for use, lens function and material characteristics of the **Acuity 181™ (tisilfocon A)** and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG®** Rigid Gas Permeable Contact Lenses, as well as the predicate devices.

Substantial Equivalence Matrix

	Acuity 181™ (tisilfocon A) and **Acuity 181™** (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses	Hyper GP (tisilfocon A) Daily Wear Contact Lens	Visionary Optics Scleral Contact Lens (tisilfocon A)	Acuity200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens; Acuity 100™ (hexafocon A) Rigid Gas Permeable Contact Lens; Acuity 200™ with Tangible® Hydra-PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens; Acuity 100™ with Tangible® Hydra-PEG® (hexafocon A) Rigid Gas Permeable Contact Lens
510(k) Number	Subject Device	Predicate Device	Predicate Device	Predicate Device
		K182304	K223394	K240618
Functionality	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina
Intended Use	Daily Wear	Daily Wear	Daily Wear	Daily Wear
Indication for Use	The Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® SPHERICAL Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® TORIC Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear 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 10.00 diopters. The Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® MULTIFOCAL/BIFOCAL Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear 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 4.00 diopters and are presbyopic requiring add power of up to +4.00 diopters. The Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® IRREGULAR CORNEA Daily Wear Contact Lens may be	The Hyper GP (tisilfocon A) SPHERICAL Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear for the correction of refractive error in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. The Hyper GP (tisilfocon A) TORIC Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear 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 10.00 diopters. The Hyper GP (tisilfocon A) MULTIFOCAL/BIFOCAL Rigid Gas Permeable (RGP) Contact Lens is indicated for daily wear 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 4 diopters and are presbyopic requiring add power of up to +4.00 diopters. The Hyper GP (tisilfocon A) IRREGULAR CORNEA Daily Wear Contact Lens may be prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular	The Visionary Optics Scleral Contact Lens for daily wear is indicated for use for the management of multiple ocular conditions, such as, degenerations that lead to an irregular corneal shape (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's Nodular Degeneration), dystrophies (e.g. Cogan's dystrophy, Granular Corneal Dystrophy, Lattice Corneal Dystrophy,), post-surgery (e.g. corneal transplant, LASIK, radial keratotomy), and corneal scarring from infection or trauma. The Visionary Optics Scleral Contact Lens for daily wear is also indicated for therapeutic. management of ocular surface disease including dry eye (e.g. ocular manifestations of Graft-versus- Host disease, Sjogren's syndrome, dry eye syndrome), limbal stem cell deficiency (e.g. Stevens- Johnson syndrome, chemical and thermal burns, radiation, filamentary keratitis), epidermal ocular disorders, disorders of the skin (e.g. atopy, ectodermal dysplasia),	The Acuity 200™ (fluoroxyfocon A), Acuity 100™ (hexafocon A), Acuity 200™ with Tangible® Hydra-PEG® (fluoroxyfocon A), and Acuity 100™ with Tangible® Hydra-PEG® Rigid Gas Permeable Contact Lenses are indicated for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be prescribed for daily wear in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g.,

	prescribed in otherwise non-diseased eyes that require a rigid gas permeable lens for the management of irregular corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery. The Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® ORTHOKERATOLOGY contact lenses are indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters with eyes having astigmatism up to 1.50 diopters in non-diseased eyes. To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule. Furthermore, eyes suffering from certain ocular surface disorders may benefit from the physical protection, aqueous hydrated environment and the saline bath provided by scleral lens designs. Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® (tisilfocon A) SCLERAL lenses are indicated for therapeutic use for the management of irregular and distorted corneal surfaces where the subject: 1 . cannot be adequately corrected with spectacle lenses 2. requires a rigid gas permeable contact lens surface to improve vision 3. is unable to wear a corneal rigid gas permeable lens due to corneal distortion or surface irregularities. Common causes of corneal distortion include but are not limited to corneal infections, trauma, tractions as a result of scar formation secondary to refractive surgery (e.g. LASIK or radial keratotomy) or corneal transplantation. Causes may also include corneal degeneration (e.g. keratoconus, keratoglobus, pellucid marginal degeneration, Salzmann's nodular degeneration) and corneal dystrophy (e.g., lattice dystrophy, granular corneal dystrophy, Reis-Bucklers dystrophy, Cogan's dystrophy). The Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® (tisilfocon A) SCLERAL lenses are indicated for therapeutic use in eyes with ocular surface disease (e.g. ocular Graft-versus-Host disease, Sjogren's syndrome, dry eye syndrome and Filamentary Keratitis}, limbal stem cell deficiency (e.g. Stevens-Johnson syndrome,	corneal conditions such as; keratoconus, pellucid marginal degeneration or following penetrating keratoplasty or refractive (e.g. LASIK) surgery. The Hyper GP (tisilfocon A) ORTHOKERATOLOGY contact lenses are indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes. To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule. Eyecare practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.	neurotrophic keratitis e.g. Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g. anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for distorted cornea or ocular surface disease, the Visionary Optics Scleral Contact Lens may incidentally provide correction of refractive error in persons with myopia, hyperopia, astigmatism or presbyopia. Eye care practitioners may prescribe the lenses for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.	LASIK) surgery. The Acuity 200™ (fluoroxyfocon A), Acuity 100™ (hexafocon A), Acuity 200™ with Tangible® Hydra-PEG® (fluoroxyfocon A), and Acuity 100™ with Tangible® Hydra-PEG® Rigid Gas Permeable Contact Lenses are also indicated for therapeutic use in eyes with ocular surface disease (e.g. ocular Graft-versus-Host disease, Sjögren's syndrome, dry eye syndrome and Filamentary Keratitis), limbal stem cell deficiency (e.g. Stevens-Johnson syndrome, chemical radiation and thermal burns), disorders of the skin (e.g. atopy, ectodermal dysplasia), neurotrophic keratitis (e.g. Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g. anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the lens may concurrently provide correction of refractive error. The Acuity 200™ (fluoroxyfocon A), Acuity 100™ (hexafocon A), Acuity 200™ with Tangible® Hydra-PEG® (fluoroxyfocon A), and Acuity 100™ with Tangible® Hydra-PEG® Rigid Gas Permeable Contact Lenses may be cleaned and disinfected using a chemical (not heat) lens care system.

	chemical radiation and thermal burns), disorders of the skin (e.g. atopy, ectodermal dysplasia), neurotrophic keratitis (e.g. Herpes simplex, Herpes zoster, Familial Dysautonomia), and corneal exposure (e.g. anatomic, paralytic) that might benefit from the presence of an expanded tear reservoir and protection against an adverse environment. When prescribed for therapeutic use for a distorted cornea or ocular surface disease, the Acuity 181™ (tisilfocon A) and Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® (tisilfocon A) (tisilfocon A) SCLERAL lenses may concurrently provide correction of refractive error. Eyecare practitioners may prescribe the lenses or frequent/ planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be cleaned and disinfected using a chemical (not heat) lens care system.			
Product Code	HQD, MUW	HQD, MUW	HQD	HQD
FDA Group #	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate
Classification	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916	Class II Lenses, Rigid Gas Permeable, Daily Wear 21 CFR 886.5916
Material (USAN)	Tisilfocon A	Tisilfocon A	Tisilfocon A	Fluoroxyfocon A
Production Method	Lathe Cut	Lathe Cut	Lathe Cut	Lathe Cut
Water Content (%)	<1%	<1%	<1%	<1%
Specific Gravity	1.22	1.20	1.20	1.18
Oxygen Permeability, Dk, ISO/Fatt Method 10^{-11} (cm^3 O_2 x cm/ (cm^2 x sec x mmHg)@ 35°C	181 $x10^{-11}$	180 $x10^{-11}$	180 $x10^{-11}$	200 $x10^{-11}$
UV Absorber Available	Yes	Yes	Yes	Yes
Plasma Treatment	Yes, Optional	Yes, Optional	Yes, Optional	Yes, Optional
Hydra-PEG Surface Coating	Yes, Optional	Yes, Optional	Yes, Optional	Yes, Optional

VII. PERFORMANCE DATA

Non-Clinical Studies

A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the **Acuity 181™ (tisilfocon A)** and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses**. All non-clinical toxicology tests were conducted in accordance with the GLP regulation. All other testing was conducted according to valid scientific protocols. Test results of the non- clinical testing on the **Acuity 181™ (tisilfocon A)** and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses** demonstrate that:

- The finished lenses (uncoated and coated with Tangible™ Hydra-PEG®) are not cytotoxic per ISO 10993-5, not acutely systemically toxic per ISO 10993-11, and does not solicit an acute ocular irritation response per ISO 10993-23,
- The physicochemical, mechanical, and optical properties of the Tangible™ Hydra-PEG® coated and uncoated lenses are substantially equivalent to the predicate devices.
- Bioburden levels are below the acceptance criteria (<100 CFU/lens) initially and following 30 days of storage in Bausch & Lomb's Boston® Simplus Multi-Action Solution at ambient temperatures,
- Physical parameters are stable following 30 days of storage in Bausch & Lomb's Boston® Simplus Multi-Action Solution at ambient temperatures, and
- The Tangible™ Hydra-PEG® coated and uncoated tisilfocon A lenses are physically compatible with currently marketed care solutions.

Clinical Studies

Clinical performance data to demonstrate the safety and effectiveness of contact lenses manufactured from tisilfocon A has been previously addressed.

VIII. CONCLUSIONS

Substantial Equivalence

Lastly, information presented in this Premarket Notification establishes **Acuity 181™ (tisilfocon A)** and **Acuity 181™ (tisilfocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses** as safe and effective as the predicate device(s) when used in accordance with the labeled instructions for use and for the proposed indications.

Risks and Benefits

The risks of the subject device are the same as those normally attributed to the wearing of rigid gas permeable (RGP) daily wear contact lenses. The benefits to the patient are the same as those for other RGP contact lenses.