April 3, 2024

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

Re: K240618
Trade/Device Name: 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
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: February 26, 2024
Received: March 6, 2024

Dear Bret Andre:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) 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.

510(k) Number *(if known)*
K240618

Device Name
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, and Acuity 100™ with Tangible® Hydra-PEG® (hexafocon A) Rigid Gas Permeable Contact Lens

Indications for Use *(Describe)*
The Acuity 200™ (fluoroxyfocon A), Acuity 100™ (hexafocon A), Acuity 200™ with Tangible® Hydra-PEG® (fluoroxyfocon A), and Acuity 100™ with Tangible® Hydra-PEG® (hexafocon A) 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., 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® (hexafocon A) 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® (hexafocon A) Rigid Gas Permeable Contact Lenses 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.

SPECIAL 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: K240618

I. SUBMITTER

Date Prepared: March 30, 2024

Name: **Acuity Polymers, Inc.**
Address: 1667 Lake Avenue, Suite 354
Rochester, NY 14615
United States

Contact Person: James A. Bonafini, Jr
President
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Consultant: Bret Andre
Andre Vision and Device Research
6119 Canter Ln.
West Linn, OR 97068
Phone number: (503) 372-5226

II. DEVICE

Trade Name: **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

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

~Reason for Submission~ *Indications for Use Change*

III. PREDICATE DEVICE

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 for daily wear are substantially equivalent to the following predicate devices:

- "Visionary Optics Scleral Contact Lens (roflufocon D, roflufocon E, hexafocon A, hexafocon B, tisilfocon A, fluoroxyfocon A)"
  By Visionary Optics LLC
  510(k) number; **K233325**
  Product Code: HQD
- "Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens"
  By Acuity Polymers, Inc.
  510(k) number; **K201194**
  Product Code: HQD
- "Acuity 100™ (hexafocon A) Rigid Gas Permeable Contact Lens"
  By Acuity Polymers, Inc.
  510(k) number; **K162005**
  Product Code: HQD
- Acuity 200 with Tangible® Hydra-PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens
  By Acuity Polymers, Inc.
  510(k) number; **K213538**
  Product Code: HQD
- "Acuity 100™ (hexafocon A) with Tangible® Hydra-PEG®, TYRO™-97 (hofocon A) with Tangible® Hydra-PEG® Rigid Gas Permeable Contact Lens"
  By Acuity Polymers, Inc.
  510(k) number; **K230965**
  Product Code: HQD
- "OPTIMUM GP (roflufocon D, roflurocon E) Daily Wear Contact Lens, HEXA100 (hexafocon A) Daily Wear Contact Lens"
  By Contamac Ltd.
  510(k) number; **K180616**
  Product Code: HQD

IV. DEVICE DESCRIPTION

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 manufactured from machine latheable rigid gas permeable materials composed of siloxanyl fluoromethacrylate copolymers that are tinted for visibility and available with or without an ultraviolet (UV) light absorbers.

Acuity 200™ with Tangible® Hydra-PEG® (fluoroxyfocon A), and Acuity 100™ with Tangible® Hydra-PEG® Rigid Gas Permeable Contact Lenses are treated to incorporate Hydra-PEG Technology developed by Tangible Sciences. This PEG polymer is permanently attached to the surface and is designed to enhance surface (wetting) properties while not affecting the

mechanical or optical properties of the underlying material.

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 for daily wear are made available in spherical, toric, multifocal, scleral and aspheric designs in the following lens parameters:

Parameter	Range	Tolerance
Base Curve	4.00mm to 11.50mm	± 0.05 mm
Center Thickness	0.08mm to 0.75mm	± 0.02 mm
Diameter	7.0mm to 21.0mm	± 0.10mm
Spherical Power	-20.00D to +20.00D	± 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	Up to 9.00D	± 0.25 (0 to </= 2D) ± 0.37 (2 to </= 4D) ± 0.50 (over 4D)
Multifocal Power	+1.00D to 4.00D	± 0.25D
Surface Appearance	-	Lenses should be clear with no surface defect

The following table depicts the physical properties of the Acuity 200™ (fluoroxyfocon A) and Acuity 200™ with Tangible® Hydra-PEG® Rigid Gas Permeable Contact Lens:

	Fluoroxyfocon A Rigid Gas Permeable Contact Lens
Refractive Index	1.430
Modulus (MPa)	1194
Hardness (Shore D)	78
Specific Gravity	1.18
Oxygen Permeability (Dk)	200×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)
Color Additives	Visibility Tints – D&C Green #6, D&C Violet #2, Solvent Yellow 18, D&C Red #17

The following table depicts the physical properties of the Acuity 100™ and Acuity 100™ with Tangible® Hydra-PEG® (hexafocon A) Rigid Gas Permeable Contact Lens:

	Hexafocon A Rigid Gas Permeable Contact Lens
Refractive Index	1.415
Modulus (MPa)	1496
Hardness (Shore D)	80
Specific Gravity	1.27
Oxygen Permeability (Dk)	111×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C)
Color Additives	Visibility Tints – D&C Green #6, D&C Violet #2, Solvent Yellow 18

The following table depicts the shipping method, storage solution for wet shipping, and shipping case used for each lens model:

MODEL	Acuity 200 (fluoroxyfocon A)	Acuity 100 (hexafocon A)	Acuity 200 (fluoroxyfocon A) with Tangible Hydra-PEG	Acuity 100 (hexafocon A) with Tangible Hydra-PEG
Ship Method	Dry	Dry	Dry or Wet*	Dry or Wet*
Storage Solution	N/A	N/A	Menicon Unique pH Multi-purpose Solution (K130805) & Boston Simplus® Multi-Action Solution (K024289)	Menicon Unique pH Multi-purpose Solution (K130805) & Boston Simplus® Multi-Action Solution (K024289)
Shipping Case	Deep Well Lens Case (K171539)	Deep Well Lens Case (K171539)	Deep Well Lens Case (K171539)	Deep Well Lens Case (K171539)

* Lenses coated with Tangible Hydra-PEG are stored wet.

V. INDICATIONS FOR USE

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., 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses and Acuity 100™ (hexafocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to the predicate device (cleared under K233325) in terms of the following:

- Intended use – daily wear contact lenses
- Indications for use – Therapeutic (irregular cornea and ocular surface disease)
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- USAN materials (fluoroxyfocon A and hexafocon A)
- Production method – lathe cut

The Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to the predicate device (cleared under K201194) in terms of the following:

- Intended use – daily wear contact lenses
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- USAN material (fluoroxyfocon A)
- Lens designs
- Production method – lathe cut (same facility, processes, and quality control procedures)
- Final packaging and shipping

The Acuity 100™ (hexafocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to the predicate device (cleared under K162005) in terms of the following:

- Intended use – daily wear contact lenses
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- USAN material (hexafocon A)
- Lens designs
- Production method – lathe cut (same facility, processes, and quality control procedures)
- Final packaging and shipping

The Acuity 200™ with Tangible® Hydra-PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to the predicate device (cleared under K213538) in terms of the following:

- Intended use – daily wear contact lenses
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- USAN material (fluoroxyfocon A)
- Available with Tangible® Hydra-PEG®
- Lens designs

- Production method – lathe cut (same facility, processes, and quality control procedures)
- Final packaging and shipping

The Acuity 100™ with Tangible® Hydra-PEG® (hexafocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to the predicate device (cleared under K230965) in terms of the following:

- Intended use – daily wear contact lenses
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- USAN material (hexafocon A)
- Available with Tangible® Hydra-PEG®
- Lens designs
- Production method – lathe cut (same facility, processes, and quality control procedures)
- Final packaging and shipping

The Acuity 200™ with Tangible® Hydra-PEG® (fluoroxyfocon A) Acuity 100™ with Tangible® Hydra-PEG® (hexafocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to the predicate device (cleared under K180616) in terms of the following:

- Intended use – daily wear contact lenses
- Classification – Lenses, Rigid Gas Permeable, Daily Wear (21 CFR 886.5916)
- FDA material group – group # 3 fluoro silicone acrylate
- USAN material (hexafocon A)
- Available with Tangible® Hydra-PEG®
- Indications for use – Therapeutic (irregular cornea and ocular surface disease)

The following matrix illustrates the production method, lens function and material characteristics of 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, as well as the predicate devices.

	Acuity 200™ Acuity 100™ Rigid Gas Permeable Contact Lens	**Visionary Optics Scleral Contact Lens**	**Acuity 200™ Rigid Gas Permeable Contact Lens**	**Acuity 100™ Rigid Gas Permeable Contact Lens**	**Acuity 200™ with Tangible® Hydra-PEG®**	**Acuity 100™ TYRO™ 97 with Tangible® Hydra-PEG®**	**OPTIMUM GP HEXA100 Daily Wear Contact Lens**
	Subject Device	**Predicate Device (K233325)**	**Predicate Device (K201194)**	**Predicate Device (K162005)**	**Predicate Device (K213538)**	**Predicate Device (K230965)**	**Predicate Device (K180616)**
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	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
Product Code	HQD	HQD	HQD	HQD	HQD	HQD	HQD
FDA Group #	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate	Group # 3 Fluoro Silicone Acrylate
Material (USAN)	fluoroxyfocon A, hexafocon A	roflufocon D, roflufocon E, hexafocon A, hexafocon B, tisilfocon A, fluoroxyfocon A	fluoroxyfocon A	hexafocon A	fluoroxyfocon A	hexafocon A; hofocon A	hexafocon A; roflufocon D; roflufocon E
Production Method	Lathe-Cut	Lathe-Cut	Lathe-Cut	Lathe-Cut	Lathe-Cut	Lathe-Cut	Lathe-Cut
Intended Use	Daily Wear	Daily Wear	Daily Wear	Daily Wear	Daily Wear	Daily Wear	Daily Wear
Water Content (%)	<1%	<1%	<1%	<1%	<1%	<1%	<1%
UV Absorber Available	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hydra-PEG® Coating Available	Yes	No	No	No	Yes	Yes	Yes

	Indications for Use
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 s **(Subject Device)**	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., 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.
Visionary Optics Scleral Contact Lens (roflufocon D, roflufocon E, hexafocon A, hexafocon B, tisilfocon A, fluoroxyfocon A) (K233325)	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), 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.
Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens (K201194)	The Acuity 200™ (fluoroxyfocon A) 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 lens may be prescribed in spherical and aspheric powers ranging from -20.00 D to +20.00 D for daily wear.
Acuity 100™ (hexafocon A) Rigid Gas Permeable Contact Lens (K162005)	The Acuity 100™ (hexafocon A) 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 lens may be prescribed in spherical and aspheric powers ranging from -20.00 D to +20.00 D for daily wear. 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., LASIK) surgery. The lens may be disinfected using a chemical disinfection system only.
Acuity 200™ with Tangible®	Acuity 200™ with Tangible® Hydra PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens is indicated for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or

Hydra-PEG® Rigid Gas Permeable Contact Lens (K213538)	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., LASIK) surgery. The Acuity™ 200 with Tangible® Hydra-PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens may be cleaned and disinfected using a chemical (not heat) lens care system.
Acuity 100™ and TYRO™ 97 with Tangible® Hydra-PEG® Rigid Gas Permeable Contact Lenses (K230965)	Acuity™ 100 (hexafocon A) 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., LASIK) surgery. The lens may be disinfected using a chemical disinfection system only. TYRO™-97 (hofocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses are indicated for daily wear for the correction of visual acuity in non-aphakic persons with non-diseased eyes that are myopic, hyperopic or presbyopic and which may exhibit corneal astigmatism. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a gas permeable contact 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 lenses may be disinfected only by using chemical disinfection.
OPTIMUM GP (roflufocon D, roflurocon E) Daily Wear Contact Lens, HEXA100 (hexafocon A) Daily Wear Contact Lens (K180616)	OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses are indicated for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and non aphakic persons with non-diseased eyes. Also, the lenses may be prescribed 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 surgery. 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. OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact 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 OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear 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 OPTIMUM GP (roflufocon D, roflufocon E) and HEXA100 (hexafocon A) Daily Wear Contact Lenses may concurrently provide correction of refractive error. The lenses may be disinfected using a chemical disinfection (not heat) system only

VII. PERFORMANCE DATA

~ Non-Clinical Studies ~

Non-clinical testing to demonstrate the safety and effectiveness of 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 have been addressed through previously cleared 510(k) premarket notifications as described in the following table:

	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**
Manufacturing Design Verification	K201194	K162005	K213538	K230965
Physicochemical and Mechanical Property Testing	K201194	K162005	K213538	K230965
Extraction Studies	K201194	K162005	K213538	K230965
Bioburden Testing	K201194	K162005	K213538	K230965
Solution Compatibility	K201194	K162005	K213538	K230965
Shelf-Life Studies	K201194	K162005	K213538	K230965
Biocompatibility	K201194	K162005	K213538	K230965

~ Clinical Studies ~

Clinical performance of the ocular surface disease indication was addressed for fluoroxyfocon A and hexafocon A scleral contact lenses in 510(k) K233325.

VIII. CONCLUSIONS

Substantial Equivalence

Information presented in this premarket notification establishes that 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 for daily wear are as safe and effective as the predicate devices when used in accordance with the labeled directions for use and for the proposed indications.

Risks and Benefits

The risks of 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 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.