June 16, 2023

Acuity Polymers, Inc.
Jose Chavez
Director, Regulatory Affairs
1667 Lake Ave
Building 59, Suite 303
Rochester, NY 14615

Re: K230965
Trade/Device Name: Acuity 100™ (hexafocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lens , TYRO™-97 (hofocon A) with Tangible™ Hydra-PEG® 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: March 31, 2023
Received: April 5, 2023

Dear Jose Chavez:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230965

Device Name
Acuity 100™ (hexafocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lens, TYRO™-97 (hofocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lens

Indications for Use *(Describe)*

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.

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: K230965

I. SUBMITTER

Date Prepared:	June 8th, 2023
Name:	Acuity Polymers, Inc.
Address:	1667 Lake Ave. Building 59, Suite 303 Rochester, NY 14615 USA
Contact Person:	Jose Chavez Director, Regulatory Affairs
Phone number:	(585) 458-8409
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II. DEVICE

Trade Name:	Acuity 100™ (hexafocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lens TYRO™-97 (hofocon A) with Tangible™ Hydra-PEG® 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

Purpose of the 510(k) Submission:

Acuity 100™ (hexafocon A) and TYRO™-97 (hofocon A) Rigid Gas Permeable Contact Lenses, cleared under 510(k) K162005, K180988, K052507 and K102154 are modified to include Tangible™ Hydra-PEG® surface coating, which is a thin, polyethylene glycol (PEG) based polymer designed to improve the wettability of the contact lenses. Specifically, Tangible™ Hydra-PEG® treated contact lenses demonstrate a measurable improvement in the contact angle compared to untreated lenses.

III. PREDICATE DEVICE

Acuity 100™ (hexafocon A) with Tangible™ Hydra-PEG® is substantially equivalent to predicate devices: Acuity 100™ (hexafocon A) Rigid Gas Permeable Contact Lens 510(k) numbers K162005 and K180988.

TYRO™-97 (hofocon A) with Tangible™ Hydra-PEG® is substantially equivalent to predicate devices: TYRO™-97 (hofocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses for Daily Wear, 510(k) numbers K052507 and K102154

Acuity 100™ (hexafocon A) with Tangible™ Hydra-PEG® and **TYRO™-97 (hofocon A) with Tangible™ Hydra-PEG®** are substantially equivalent to predicate device:

Boston XO® (hexafocon A) Rigid Gas Permeable Contact Lenses with Tangible™ Hydra-PEG Rigid Gas Permeable Contact Lenses, 510(k) number K183167.

IV. DEVICE DESCRIPTION

Acuity 100™ (hexafocon A) are available as lathe cut rigid gas permeable contact lenses for daily wear only. The lenses are manufactured from a currently marketed contact lens material, hexafocon A, comprised of a siloxanyl fluoromethacrylate copolymer (fluorosilicone acrylate monomers), tinted for visibility, and with or without UV light absorber. Non-proprietary names were assigned by the United States Adopted Names Council (USAN).

Acuity 100™ (hexafocon A) Rigid Gas Permeable Contact Lenses are treated to incorporate **Tangible™ Hydra-PEG®** surface coating, which is a thin, polyethylene glycol (PEG) based polymer that is covalently 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 treated with **Tangible™ Hydra-PEG®** , the underlying material is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (sessile drop contact angle) compared to untreated lenses.

TYRO™-97 (hofocon A) Rigid Gas Permeable Contact Lenses are available as lathe cut rigid gas permeable contact lenses for daily wear only. The lenses are manufactured from currently marketed contact lens material, hofocon A, polymer of trifluoroethyl methacrylate and silicone

methacrylate (fluorosilicone acrylate monomers), tinted for visibility, with or without UV light absorber. Non-proprietary names were assigned by the United States Adopted Names Council (USAN).

TYRO™-97 (hofocon A) Rigid Gas Permeable Contact Lenses are treated to incorporate **Tangible™ Hydra-PEG®** surface coating, which is a thin, polyethylene glycol (PEG) based polymer that is covalently 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 treated with **Tangible™ Hydra-PEG®** ,the underlying material is encapsulated in a thin layer of polymer that results in measurable improvement of wettability (sessile drop contact angle) compared to untreated lenses.

The surface properties of: **Acuity 100™ (hexafocon A)**, and **TYRO™-97 (hofocon A)** materials uncoated and coated with **Tangible™ Hydra-PEG®** are depicted in the following table:

	Acuity 100™ (hexafocon A)	**TYRO™-97 (hofocon A)**
Sessile Drop Contact Angle	Coated: <10° Uncoated: 56°	Coated: <10° Uncoated:23.3°

Acuity 100™ (hexafocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses are available in the same design configurations and available parameters as the predicate devices, cleared under K162005 and K180988.

TYRO™-97 (hofocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses are available in the same design configurations and available parameters as the predicate devices, cleared under K052507 and K102154.

V. INDICATION FOR USE

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

ACUITY 100™ (hexafocon A) WITH TANGIBLE™ HYDRA-PEG®

Acuity 100™ (hexafocon A) with Tangible™ Hydra-PEG® surface coating technology is substantially equivalent to Acuity 100™ (hexafocon A) uncoated lenses (primary predicate devices cleared under K162005 and K180988 in terms of the following:

1. Proprietary contact lens material formulation and USAN
2. Intended Use- Daily wear contact lens.
3. Indication for Use
4. Lens Designs and available parameters

Acuity 100™ **(**hexafocon A) with Tangible™ Hydra-PEG® surface coating technology is substantially equivalent to Boston XO® (hexafocon A) Rigid Gas Permeable Contact Lenses with Tangible™ Hydra-PEG (secondary Predicate device cleared under K183167) in terms of the following:

1. USAN name
2. Intended use- Daily wear contact lens.
3. Indication for use- similar
4. Tangible™ HYDRA-PEG® surface coating

TYRO™-97 (hofocon A) WITH TANGIBLE™ HYDRA-PEG®

TYRO™-97 (hofocon A) with Tangible™ Hydra-PEG® surface coating technology is substantially equivalent to TYRO™-97 (hofocon A) uncoated lenses (primary predicate devices cleared under K052507 and K102154) in terms of the following:

1. Proprietary contact lens material formulation and USAN
2. Intended Use- Daily wear contact lens.
3. Indication for Use
4. Lens Designs and available parameters

TYRO™-97 (hofocon A) with Tangible™ Hydra-PEG® surface coating technology is substantially equivalent to Boston XO® (hexafocon A) Rigid Gas Permeable Contact Lenses with Tangible™ Hydra-PEG (Secondary Predicate device cleared under K183167) in terms of the following:

1. Thermoset copolymers derived from fluorosilicone acrylate monomers.
2. Intended Use- Daily wear contact lens.
3. Indication for use- similar
4. Tangible™ Hydra-PEG® surface coating

The following **Substantial Equivalence Matrix** illustrates the production method, intended use, and material characteristics of Acuity 100™ **(**hexafocon A) with Tangible™ Hydra-PEG® and TYRO™-97 (hofocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses as well as the predicate devices.

	Acuity 100™ (hexafocon A) **with Tangible™ Hydra-PEG®**, **TYRO™-97** (hofocon A) **with Tangible™ Hydra-PEG®**	**Acuity 100™** (hexafocon A) Rigid Gas Permeable Contact Lens	**TYRO™ -97** (hofocon A) Rigid Gas Permeable Contact Lens	**Boston XO®** (hexafocon A) **with Tangible™ Hydra-PEG**
	New Device	**Predicate Device** (K162005, K180988)	**Predicate Device** (K052507, K102154)	**Predicate Device** K183167
Intended Use	Daily Wear	Daily Wear	Daily Wear	Daily Wear
Device Name	Acuity 100™ (hexafocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lens TYRO™-97 (Hofocon A) with Tangible™ Hydra PEG® Rigid Gas Permeable Contact Lenses	Acuity 100™ (hexafocon A) Rigid Gas Permeable Contact Lens	TYRO™-97 (hofocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lenses for Daily Wear	Boston XO® (hexafocon A) Rigid Gas Permeable Contact Lenses with Tangible™ Hydra-PEG Rigid Gas Permeable Contact Lenses

Indication for Use	**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 Lens 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.	The **Acuity l00™** (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. The lenses may be stored in a multipurpose solution (BOSTON SIMPLUS or Menicon Unique pH) solution up to 30 days.	**TYRO™-97** (hofocon A) Rigid Gas Permeable Spherical, Aspheric, Toric and Bifocal Contact Lens is indicated for daily wear for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopic, hyperopic or presbyopic and which may exhibit corneal astigmatism**.** The lenses may be disinfected only by using chemical disinfection. **TYRO™-97** (hofocon A) Rigid Gas Permeable Contact Lenses is 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	**The Boston XO® (hexafocon A) with Tangible™ Hydra-PEG** Contact Lens is indicated for daily wear 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 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 Boston XO®** (hexafocon A) **with Tangible™ Hydra-PEG** lens may be disinfected using a chemical disinfection system (not heat) only.
Power Range	hexafocon A -20.00 D to +20.00 D hofocon A -20.00 D to +12.00 D	hexafocon A -20.00 D to +20.00 D	hofocon A -20.00 D to +12.00 D	hexafocon A -20.00 D to +20.00 D
Production Method	Lathe Cut	Lathe Cut	Lathe Cut	Lathe Cut
USAN Name	hexafocon A hofocon A	hexafocon A	hofocon A	hexafocon A

Water Content (%)	< 1%	< 1%	< 1%	< 1%
Wettability (Sessile Drop Advancing Contact Angle)	hexafocon A: <10° hofocon A: <10°	hexafocon A: 56°	hofocon A: 23.3°	(uncoated) hexafocon A: 63.4° (coated) hexafocon A: 10°
Lens Type	RGP	RGP	RGP	RGP
Available with or without UV Blocker	Yes	Yes	Yes	Yes
Lenses may be disinfected using a Chemical Disinfection System	Yes	Yes	Yes	Yes
Includes Tangible™ Hydra PEG®	Yes	No	No	Yes

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of Acuity 100™ (hexafocon A) with Tangible™ Hydra-PEG® and TYRO™-97 (hofocon 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 device demonstrate that:

Performance Testing- Bench

1. The physical properties of the lenses are stable following 30 (thirty) disinfection cycles in Boston Simplus disinfection solution at ambient temperatures.
2. The physicochemical and mechanical properties of the contact lenses are unchanged after the addition of Tangible™ Hydra-PEG®, with the exception of wettability (contact angle).
3. The surface properties of the lens are stable following 30 (thirty) days of accelerated aging.
4. Bioburden levels are below the acceptance criteria (<100 CFU/lens) initially and following 30 (thirty) days of storage in solution at ambient temperatures.

Performance Testing- Animal

5. Acute Ocular Irritation testing per ISO 10993-23 and Acute Systemic Toxicity testing per ISO 10993-11 were performed for both the final finished subject devices.

Performance Testing- In Vitro

6. Cytotoxicity testing per ISO 10993-5 was performed for both the final finished subject devices.

Performance Testing -Clinical

The clinical safety and effectiveness of finished rigid gas permeable contact lenses manufactured from Acuity™ 100 (hexafocon A) and TYRO™-97 (hofocon A) Rigid Gas Permeable Contact Lenses materials have been demonstrated by predicate devices. Additionally, the clinical safety and effectiveness for contact lenses treated with Tangible™ Hydra-PEG® has been previously demonstrated.

VIII. CONCLUSIONS

Validity of Scientific Data

Laboratories under Good Laboratory Practice regulations conducted toxicology, microbiology, and shelf-life stability studies following scientific protocols. The data were determined to be scientifically valid under 21 CFR §860.7.

Substantial Equivalence

Information presented in this 510(k) Premarket Notification establishes that the Acuity 100™ (hexafocon A) with Tangible™ Hydra-PEG® and TYRO™-97 (hofocon A) with Tangible™ Hydra-PEG® Rigid Gas Permeable Contact Lenses are as safe and effective as the predicate devices 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 rigid gas permeable (RGP) daily wear contact lenses. The benefits to the patient are the same as those for other RGP contact lenses.