December 30, 2021

Acuity Polymers, Inc.
James A. Bonafini, Jr.
President & COO
1667 Lake Ave. Suite 303
Rochester, NY 14615

Re: K213538
Trade/Device Name: Acuity 200™ Tangible® Hydra PEG® (fluoroxyfocon 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: November 5, 2021
Received: November 8, 2021

Dear James Bonafini:

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, 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)*
K213538

Device Name

Acuity 200™ with Tangible® Hydra PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens

Indications for Use *(Describe)*

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 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.

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

The assigned 510(k) number is K213538

SUBMITTER

Date Prepared: November 5, 2021

Name and Address: Acuity Polymers, Inc.
1667 Lake Avenue, Suite 354
Rochester, NY 14615
(585) 458-8409

Contact Persons: James A. Bonafini, Jr. President
Telephone: (585) 458-8409
E-Mail: Jim.bonafini@acuitypolymers.com

DEVICE Common Name: Daily Wear Contact Lens

Proprietary Name: Acuity 200™ with Tangible® Hydra PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens

Device Classification: Lenses, Rigid Gas Permeable, Daily Wear Contact Lens; Class II (21 CFR 886.5916)

Device Product Code: HQD

PREDICATE DEVICES Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens (K201194)

Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens (K203571)

Optimum GP with HPT (roflufocon C, D, and E Daily Wear Contact Lenses (K161100)

DEVICE DESCRIPTION

Acuity 200™ with Tangible® Hydra PEG® (fluoroxyfocon 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. Acuity 200™ with Tangible® Hydra PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens is 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.

Acuity 200™ with Tangible® Hydra PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses are daily wear rigid gas permeable contact lenses:

- in the power range of -20.00 to +20.00 diopters for spheres
- with base curves of 4.0 mm to 11.50 mm
- with base curve chord of 6.0 mm to 6.5 mm
- with diameters of 7.0 to 21.0 mm

The lens material incorporates an ultraviolet light absorber and lenses are lathe cut in the following designs: spherical, toric, multifocal, scleral and aspheric surfaces in visibility tinted material. The device herein described is substantially equivalent to Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens (K201194), Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens (K203571) and the Optimum GP with HPT (roflufocon C, D, and E) Daily Wear Contact Lenses (K161100)

INDICATIONS FOR USE

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 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.

PERFORMANCE DATA

Non-clinical Studies

Biocompatibility Testing

Biocompatibility evaluation was conducted on the Acuity 200™ with Tangible® Hydra PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens in accordance with ISO 10993-1:2018 “Biological Evaluation of Medical Devices”. The following tests were performed:

1. Cytotoxicity – Agar Diffusion
2. Systemic Toxicity
3. Ocular Irritation

Performance Testing

To establish the performance of Acuity 200™ with Tangible® Hydra PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens**,** the follow tests were performed:

1. Lens/solution compatibility
2. Manufacturing verification
3. Contact angle Measurement
4. Accelerated Wet Shelf-Life testing
5. Lens stability testing

Comparison of Characteristics with the Predicate Device

Acuity 200™ with Tangible® Hydra PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens manufactured by Acuity Polymers, Inc. have been found to show biocompatibility, for a surface device, limited contact. In addition to biocompatibility, the chemical, mechanical and optical characteristics of the new device have been shown to be substantially equivalent to the predicate devices.

	NEW DEVICE	***PREDICATE DEVICE K201194, K203571***	***PREDICATE DEVICE***
Lens Characteristics	Acuity 200™ with Tangible® Hydra PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens	Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens	Optimum GP with HPT (roflufocon C, D, and E Daily Wear Contact Lenses (K161100)
Manufacturer	Acuity Polymers, Inc	Acuity Polymers, Inc	Contamac Ltd.
Material	fluoroxyfocon A	fluoroxyfocon A	roflufocn C, D, E
Production method	Lathe Cut	Lathe Cut	Lathe Cut
UV Blocking	Yes	Yes	Yes
Base Curves (varies with vault)	4.0 mm to 11.5 mm	4.0 mm to 11.5 mm	5.0 mm to 8.0 mm
Base Curve Chord	6.0 mm to 6.5 mm	6.0 mm to 6.5 mm	6.0 mm to 6.5 mm
Design	Standard geometry with anterior aspheric surface	Standard geometry with anterior aspheric surface	Standard & reverse geometry with anterior aspheric surface
Diameters:	7.0-21.0 mm	7.0-21.0 mm	7.0-22.0 mm
Power Range	-20.00D to +20.00D	-20.00D to +20.00D	-20.00D to +20.00D
Astigmatism range corrected	Up to 9.00 D	Up to 9.00 D	up to 10.00 D
Add Powers (for multifocal)	+1.00 D to +4.00 D	+1.00 D to +4.00 D	up to +4.00 D
Indications for Use	The 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 astigmatism) in	The Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens is 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	Indicated for the daily wear for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia and/or presbyopia. The lens may also be prescribed for the management or irregular corneal

	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.	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.	conditions such as keratoconus and post graft fitting.
Refractive Index	1.430	1.430	1.4406 (roflufocon C)
Oxygen Permeability	200	200	65
Specific Gravity	1.18	1.18	1.27
Hardness (Shore D)	78	78	NA
Modulus (MPa)	1194	1194	NA
Tint	Visibility Tints – various D&C Green #6, D&C Violet #2, Solvent Yellow 18, D&C Red #17	Visibility Tints – various D&C Green #6, D&C Violet #2, Solvent Yellow 18, D&C Red #17	Visibility Tints – various D&C Green #6, D&C Red #17, Solvent Yellow #18
Water Content	<1%	<1%	<1%
Lens Type	RGP	RGP	RGP

Clinical Studies

No clinical studies were deemed necessary for the Acuity 200™ with Tangible® Hydra PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens as Acuity 200™ fluoroxyfocon A was cleared via K201194 where clinical studies were described. Expanded indications for irregular corneas were described in K203571.

CONCLUSIONS

The non-clinical data demonstrates the safety of the device and that the device should perform as intended. The Acuity 200™ with Tangible® Hydra PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens performs substantially equivalent to the predicate devices currently marketed for the indication of correcting ametropia.