September 8, 2020

Acuity Polymers, Inc.
James A. Bonafini, Jr.
President & COO
1667 Lake Avenue, Suite 354
Rochester, NY 14615

Re: K201194
Trade/Device Name: Acuity 200™ (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: August 3, 2020
Received: August 5, 2020

Dear James A. Bonafini, Jr.:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K201194

Device Name

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

Indications for Use *(Describe)*

The Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses are indicated for daily wear and 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.

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

SUBMITTER

Date Prepared: April 30, 2020

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DEVICE

Common Name: Daily Wear Contact Lens
Proprietary Name: Acuity 200™ (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 DEVICE

Acuity 100 (hexafocon A) Rigid Gas Permeable Contact Lens (K162005).

DEVICE DESCRIPTION

The Acuity 200™ (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.

The Acuity 200™ (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 the Acuity 100 (hexafocon A) Contact Lenses described in K162005.

INDICATIONS FOR USE

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.

PERFORMANCE DATA

Non-clinical Studies

Biocompatibility Testing

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

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

Performance Testing

To establish the performance of Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses, the follow tests were performed:

1. Lens/solution compatibility
2. Manufacturing verification
3. Extractable testing
4. Contact angle
5. Dry shelf life
6. Lens stability testing

Comparison of Characteristics with the Predicate Device

Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lenses 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 device.

	NEW DEVICE	***PREDICATE DEVICE***
Lens Characteristics	Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens	Acuity 100 (hexafocon A) Rigid Gas Permeable Contact Lens K162005
Manufacturer	Acuity Polymers, Inc	Acuity Polymers, Inc
Material	fluoroxyfocon A	hexafocon A
Production method	Lathe Cut	Lathe Cut
UV Blocking	Yes	Yes
Base Curves (varies with vault)	4.0 mm to 11.5 mm	4.0 mm to 11.5 mm
Base Curve Chord	6.0 mm to 6.5 mm	6.0 mm to 6.5 mm
Design	Standard geometry with anterior aspheric surface	Standard & reverse geometry with anterior aspheric surface
Diameters:	7.0-21.0 mm	7.0-21.0 mm
Power Range	-20.00D to +20.00D	-20.00D to +20.00D
Astigmatism range corrected	Up to 9.00 D	Up to 9.00 D
Add Powers (for multifocal)	+1.00 D to +4.00 D	+1.00 D to +4.00 D
Indications for Use	The Acuity 200™ 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 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.
Refractive Index	1.430	1.415
Oxygen Permeability	200	111
Specific Gravity	1.18	1.27
Hardness (Shore D)	78	80
Modulus (MPa)*	1194	1414
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, D&C Yellow #18
Water Content	<1%	<1%
Lens Type	RGP	RGP

*As measured at Acuity Polymers under described method.

Clinical Studies

Study Design

This study was an open-label, multi-center, randomized concurrent-control study with the treatment duration of 90 days. Seventy-four (74) subjects were enrolled in the study—of which 50 subjects wore the test lenses, Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens and 24 subjects wore the control lenses (Acuity 100 (hexafocon A) Rigid Gas Permeable Contact Lens). Subjects were evaluated at four independent clinical sites across the United States. Subjects wore the Test or Control lenses for 90 days bilaterally according to the randomization method.

Trial Objective

The objective of this study was to evaluate the safety and effectiveness of the Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens.

Study Endpoints

Effectiveness Endpoints - The primary efficacy endpoint in this evaluation was a comparison of the contact lens corrected visual acuity results reported for the Test lenses versus the Control lenses. The working hypothesis was that the visual acuity results are substantially equivalent between the Test and the Control lenses.

Safety Endpoints - The primary safety endpoint in this evaluation was the comparison of the objective findings (slit lamp observations and lens fitting and deposit characteristics), subjective symptoms and adverse events reported as associated with the Test lenses with those findings reported as associated with the Control lenses. The working hypothesis was that the findings are substantially equivalent between the Test and the Control lenses

The total enrollment across all clinical sites was 74 subjects (148 eyes) with 50 subjects (100 eyes) in the test group and 24 subjects (48 eyes) in the control group. Of the 74 subjects enrolled, 58 subjects completed the scheduled visits (40 subjects in the test group and 18 subjects in the control group).

There were 55 females and 18 males in the study (3.1 ratio female/male). The average age of the subjects was 53.2 years (53.5 years in the test group and 52.7 years in the control group). Sixty-two and two tenths percent (62.2%) of the enrolled subjects were habitual rigid contact lens wearers, 25.7% were habitual soft contact lens wearers, and 10.8% were habitual spectacle lens wearers.

Clinical Study

Fifty-eight (58) of the 74 subjects enrolled completed the study. Of the 16 discontinued subjects, 9 subjects exited prior to lens dispensing. Ten subjects discontinued from the test arm (20%) and 6 subjects discontinued from the control arm (25%). In the test arm, the reasons for discontinuation included discomfort (cited by 4 subjects), lens handling (2 subjects), poor vision (1 subject), and lens positioning/fit (1 subject); the remaining

reasons cited were not directly related to the test lens (i.e. disinterest, lost to follow up, contracted shingles).

None of the completed or discontinued eyes in the test arm reported a severity of worse (>) than grade 2 for staining, edema, vascularization, hyperemia, infiltrates or any other complication. One (1) eye in the control arm reported a severity of grade 3 for bulbar redness. All other eyes treated with the control lens reported a severity of grade 2 or lower for other findings.

The test and control lenses performed similarly with respect to subject reported symptoms, problems and complaints. Symptoms reported with the highest frequency were discomfort (control 39%, test 38%), dryness (control 42%, test 31%), and irritation (control 31%, test 31%). These results indicate no clinical difference between the incidence of symptoms reported in the test arm compared to the control arm. The adverse events that occurred in the study were similar in both arms, in terms of incidence and severity.

The test and control lenses performed equally well with regards to vision safety measures—keratometry changes, refractive changes, and best corrected visual acuity—over the 90-day treatment period. Trend analysis shows no emerging trends for test and control lenses for the duration of the study.

CONCLUSIONS

The non-clinical data demonstrates the safety of the device and demonstrates that the device should perform as intended. Clinical studies were completed and demonstrate that the Acuity 200™ Rigid Gas Permeable Contact Lens performs substantially equivalent to the predicate device currently marketed for the indication of correcting ametropia.

The clinical study results establish no clinically relevant differences between the Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens and Acuity 100 (hexafocon A) Rigid Gas Permeable Contact Lens (predicate device) with respect to biomicroscopy findings, symptoms or vision safety measures; therefore, this clinical investigation supports the claim of substantial equivalence between the two device types with regard to clinical safety and effectiveness.