DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 18, 2017

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

Re: K163254
Trade/Device Name: Acuity 18 (enflufocon 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 16, 2016
Received: November 21, 2016

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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)*
K163254

Device Name

Acuity 18™ (enflufocon A) Rigid Gas Permeable Contact Lens

Indications for Use *(Describe)*

The Acuity 18™ (enflufocon 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

ACUITY POLYMERS, INC. 510(k) Premarket Notification	**510(k) Summary**
Acuity 18™ (enflufocon A) Rigid Gas Permeable Contact Lenses	**RGP Contact Lens**

510(k) SUMMARY

1. Date Prepared — November 11, 2016

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

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

4. Identification of Device:
   - Common Name: Daily Wear Contact Lens
   - Proprietary Name: Acuity 18™ (enflufocon A) RGP
   - Device Classification: Lenses, Rigid Gas Permeable, Daily Wear Contact Lens; Class II (21 CFR 886.5916)
   - Device Product Code: HQD

5. Premarket Notification Number — not available

6. Establishment Registration Number: 3012228452

7. Owner Operator Number: 10051193

8. Description of the New Device

The Acuity 18™ (enflufocon 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 sphere
- with base curves of 4.0 mm to 11.50 mm
- with base curve chord of 6.0 mm to 6.5 mm
- with diameter of 7.0 to 21.0 mm

The lens material enflufocon A) incorporates an ultraviolet light absorber and lenses are lathe cut contact lenses in the following designs: spherical, toric, multifocal, and aspheric surfaces in visibility tinted material. The material from which these lenses are made and the contact lenses described herein are substantially equivalent to the Boston ES (AKA Boston 7-30) Material and Contact Lenses (enflufocon A) described K943177 and K053124.

These devices will not be marketed with multiple components or any required accessories.

9. Intended Use

The Acuity 18™ (enflufocon A) Rigid Gas Permeable Contact Lens 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.

10. Predicate Devices:
The Acuity 18™ (enflufocon A) RGP contact lenses for daily wear are substantially equivalent to the Boston ES (enflufocon A) Daily Wear Contact Lens (K943177). This lens was selected because it is made from an identical material and has optics designed to address the same Indications for Use.

11. Substantial Equivalence

Substantial equivalence is based on:

For design: The predicate lenses, the Boston ES RGP lenses for daily wear, have a standard or reverse lens geometry with an anterior aspheric optic surface. The new lenses, the Acuity 18™ RGP lenses for daily wear have the same substantially equivalent standard or reverse geometry with an anterior optic surface design.

For material: The predicate lens materials are comprised of a siloxanyl fluoroitaconate copolymer (enflufocon A). The new lens material also is comprised of a siloxanyl fluoroitaconate copolymer (enflufocon A).

The new lenses in this submission therefore are substantially equivalent to the lenses cleared under K943177.

12. Non-Clinical Studies

The enflufocon A lens material manufactured by Acuity Polymers, Inc. has been tested and found to meet the biocompatibility requirements listed in the FDA Daily Wear Contact Lens Guidance Document, May 1994 and ISO 10993-1 (2009) for a surface device, limited contact. The chemical, mechanical and optical characteristics of the new lens have been shown to be equivalent to the predicate lenses.

13. Clinical Studies

Clinical studies for the Acuity 18™ (enflufocon A) material have been deemed as not necessary in support of clearance of this premarket notification as no new or additional questions of safety or effectiveness have been raised as a result of the preclinical testing and evaluation of the material.

14. Packaging

The primary lens container for shipping is a flat pack card. The lenses will not be sterilized by Acuity Polymers, Inc. prior to shipment to customers.

15. Relationship to Special Controls (Guidance)

This submission requires reliance upon a guidance document to describe the change and its relevance to current guidance. The FDA Daily Wear Contact Lens Guidance Document, May 1994, is the relevant document to which this submission is based. Clinical performance data is not necessary since the material and optical design of the new lenses is substantially equivalent to the material and optical design of the predicate lenses in K943177. Both the new lenses and the predicate lens feature identical aspheric anterior optics.

16. Manufacturing & Packaging:

Finished Product Manufacturing, Inspection, Packaging and Distribution:
Acuity Polymers, Inc. (Est. Regis: #3012228452)
1667 Lake Avenue, Suite 354
Rochester, NY 14615
(585) 458-8409

17. Action Taken to Comply with FDA Special Controls:

The submission is for a daily wear contact lens, Class II subject to Special Controls. The Special Control is the FDA Daily Wear Contact Lens Guidance Document, May 1994 to which this submission is applied. All testing listed in this 510(k) submission is in accordance with that document.

ACUITY POLYMERS, INC. 510(k) Premarket Notification	**510(k) Summary**
Acuity 18™ (enflufocon A) Rigid Gas Permeable Contact Lenses	**RGP Contact Lens**

Side-by-Side Comparison

	NEW LENS	***PREDICATE LENS***
Lens Characteristics	Acuity 18™ (enflufocon A) RGP Lens	Boston ES (enflufocon A) RGP Lens
Manufacturer	Acuity Polymers, Inc	Bausch + Lomb
Material	enflufocon A	enflufocon 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 & reverse 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 18™ (enflufocon 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.	Boston ES Contact Lenses are 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.
Refractive Index (RGP)	1.445	1.443
Oxygen Permeability (RGP Center)	21	18
Specific Gravity (RGP)	1.22	1.22
Hardness (Shore D)	84	85
Modulus (MPa)	1739	1900
Tint	Visibility Tints – various D&C Green #6, D&C Violet #2, D&C Yellow #18	Visibility Tints – various D&C Green #6, D&C Violet #2, D&C Yellow #18
Water Content (Soft Skirt)	<1%	<1%
Lens Type	RGP	RGP

Conclusions

In the evaluation of RGP materials, various properties are measured to ascertain the material's ability to meet the intended application requirements. The properties which characterize the materials classification and use are refractive index, oxygen permeability, specific gravity, hardness, modulus and water content. Those properties are described in the above comparison table. These properties or characteristics are important to the function of the final lens and form the basis for the determination of use. These material values meet the minimum values required for use in the manufacture (lathing) of RGP lenses.

Based on the data generated from the chemical/physical testing (See Side by Side Comparison) of Acuity 18™ (enflufocon A) Rigid Gas Permeable Contact Lens, it is concluded that the material and contact lens made thereof meet the requirements of a daily wear rigid contact lens and is substantially equivalent to Boston ES™ (aka Boston 7-30) (enflufocon A) Daily Wear Contact Lens.