June 8, 2018

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

Re: K180988
Trade/Device Name: The Acuity 100 (hexafocon A), Acuity 85 (oprifocon A), Acuity 58 (enflufocon B) and Acuity 18 (enflufocon A) Rigid Gas Permeable Contact Lenses
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: April 13, 2018
Received: April 16, 2018

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. 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

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)*
K180988

Device Name
The Acuity 100 (hexafocon A), Acuity 85 (oprifocon A), Acuity 58 (enflufocon B) and Acuity 18 (enflufocon A) Rigid Gas Permeable Contact Lenses

Indications for Use *(Describe)*

The Acuity 100 (hexafocon A), Acuity 85 (oprifocon A), Acuity 58 (enflufocon B) and 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. The lenses may be stored in a multipurpose solution (BOSTON SIMPLUS or Menicon Unique pH) solution up to 30 days.

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.

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"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."

510(k) SUMMARY

1. Date Prepared: February 19, 2018

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 (submitter)
Telephone: (585) 458-8409
E-Mail: Jim.bonafini@acuitypolymers.com

4. Identification of Device:

Common Name: Daily Wear Contact Lens

Proprietary Name: The Acuity 100 (hexafocon A), Acuity 85 (oprifocon A), Acuity 58 (enflufocon B) and Acuity 18 (enflufocon A) Rigid Gas Permeable Contact Lenses

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

Device Product Code: HQD

5. Premarket Notification Number: K180988

6. Establishment Registration Number: 3012228452

7. Description of the New Device

a. The Acuity Polymers Rigid Gas Permeable Contact Lenses are daily wear rigid gas permeable contact lenses comprised of fluoro-silicon acrylate copolymers wet shipped in Boston SIMPLUS Multi-Action Solution.

BOSTON SIMPLUS Multi-Action Solution, a sterile, aqueous, buffered solution that contains poloxamine, hydroxyalky phosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with polyaminopropyl biguanide (0.0005%), chlorhexidine gluconate (0.003%).

b. The Acuity Polymers Rigid Gas Permeable Contact Lenses are daily wear rigid gas permeable contact lenses comprised of fluoro-silicon acrylate copolymers wet shipped in Menicon Unique pH Multi-purpose solution.

Menicon Unique-pH multi-purpose solution is a proprietary sterile, aqueous solution buffered to approximate the pH and tonicity of the eye. It contains hydroxypropyl guar,

a proprietary wetting/conditioning polymer system, polyethylene glycol, Tetronic 1304, boric acid, propylene glycol, and is preserved with polyquad (polyquaternium-1) (0.0011%), and edetate disodium (0.01%)

8. Intended Use

The Acuity 100 (hexafocon A), Acuity 85 (oprifocon A), Acuity 58 (enflufocon B) and 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. The lenses may be stored in a multipurpose solution (BOSTON SIMPLUS or Menicon Unique pH) solution up to 30 days.

9. Predicate Devices:

Boston RGP Lenses Wet Shipped in Boston SIMPLUS Multi-Action Solution as described in K073184 has been selected as the predicate device.

10. Substantial Equivalence

Substantial equivalence is based on:

Device Description	510(k)	Clearance Date
BOSTON RGP Lenses Wet Shipped in Boston Advance Comfort Formula Conditioning Solution and Stored for Up to 30 Days	K073184	02/21/2008

Acuity Polymers Rigid Gas Permeable Contact Lenses Wet Shipped in Multipurpose Solution and Stored up to 30 Days is substantially equivalent to that cleared under K073184.

11. Clinical Studies

Clinical data is not necessary as the products, both RGP lenses and multi-purpose disinfection solutions are cleared for use as indicated.

The gas permeable lens materials manufactured by Acuity Polymers, Inc. have 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.

These materials have been cleared under the following 510(k)s which include solution compatibility studies, showing stable lens parameters when using either Boston SIMPLUS Multi-Action Solution or Menicon Unique pH Multi-purpose Solutions:

RGP Lens Materials:

Device Description	510(k)	Clearance Date
Acuity 100 (hexafocon A)	K162005	12/8/2016
Acuity 18 (enflufocon A)	K163254	01/18/2017
Acuity 85 (oprifocon A)	K170001	06/02/2017
Acuity 58 (enflufocon B)	K170007	05/31/2017

Multi-action Solutions:

Storage Solution	510(k)	Clearance Date
BOSTON SIMPLUS	K024289	05/03/2003
Menicon Unique pH	K130805	07/03/2013

12. 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 stated lenses is cleared under the 510(k) process and the solutions are deemed compatible and also cleared under the 510(k) process.

13. 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

14. 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.

15. Conformance to Standards

Acuity Polymers' quality system conforms and is certified to ISO Standard 13484 (2003), Medical Devices: Quality Management Systems: Requirements for regulatory purposes.

In accordance by ISO 11737 Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products, Acuity Polymers conducts bioburden studies to monitor lens manufacturing for evidence of microorganisms.

Normally performed on non-sterile dry lenses, the testing was extended to evaluate wet storage (up to 30-days) and shipping of RGP lenses as part of the manufacturing process. It was determined that no CFUs were found at any test point during the 30-day period.

16. Conclusion

The Acuity Polymers Rigid Gas Permeable Contact Lenses Wet Shipped in Multipurpose Solution and Stored up to 30 Days is substantially equivalent to that described under K073184: "BOSTON RGP Contact Lenses Wet Shipped in BOSTON SIMPLUS Multi-Action Solution and stored up to 30 days".

Since both the RGP lenses and multi-purpose disinfection solutions are cleared and no change in indications for use is expected, it is seen that the application is equivalent to that described in K073184.

Acuity Polymers quality management system complies with The FDA Daily Wear Contact Lens Guidance Document, May 1994 and ISO 13485 (2003) Medical Devices: Quality Management Systems: Requirements for regulatory purposes.