

**K240618 Acuity 200™ (fluoroxyfocon A) Rigid Gas Permeable Contact Lens**Apr 3, 2024  
29 days to decisionK240618 · Product code: **HQD** · Ophthalmic  
Source: <https://www.510kdatabase.net/k240618/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lens, Contact (other Material) - Daily (HQD)
Date received	Mar 5, 2024
Decision date	Apr 3, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Acuity 100™ (hexafocon A) Rigid Gas Permeable Contact Lens; Acuity 200™ with Tangible® Hydra-PEG® (fluoroxyfocon A) Rigid Gas Permeable Contact Lens; Acuity 100™ with Tangible® Hydra-PEG® (hexafocon A) Rigid Gas Permeable Contact Lens

**APPLICANT**

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Company	<b>Acuity Polymers, Inc.</b>
Location	Rochester, NY, US
Contact	James A. Bonafini
510(k) history	11 submissions · 11 cleared · 2016-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Andre Vision and Device Research</b>
Contact	Bret Andre

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)