

K203571 Acuity 200 (fluoroxofocon A) Rigid Gas Permeable Contact LensApr 9, 2021
123 days to decisionK203571 · Product code: **HQD** · Ophthalmic
Source: <https://www.510kdatabase.net/k203571/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (other Material) - Daily (HQD)
Date received	Dec 7, 2020
Decision date	Apr 9, 2021
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Eyereg Consulting, Inc.
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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203571/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026