

K201194 Acuity 200™ (fluoroxofocon A) Rigid Gas Permeable Contact LensSep 8, 2020
127 days to decisionK201194 · Product code: **HQD** · Ophthalmic
Source: <https://www.510kdatabase.net/k201194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (other Material) - Daily (HQD)
Date received	May 4, 2020
Decision date	Sep 8, 2020
Days to decision	127 days
Third-party review	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201194/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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