K203571 Acuity 200 (fluoroxyfocon A) Rigid Gas Permeable Contact Lens

CLEARED

Apr 9, 2021
123 days to decision

K203571 · 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