FDA 510(k) Premarket Notification

K230627 Zilia Ocular FC (ZIL-10002)

CLEARED

Nov 20, 2023
259 days to decision

K230627 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k230627/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Mar 6, 2023
Decision date	Nov 20, 2023
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zilia, Inc.**
Location	Quebec City, CA
Contact	Sauvageau Patrick
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Ultra Life Science Solutions, Inc.**
Contact	Christina Henza

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