

K253834 VISUREF 600Mar 18, 2026
107 days to decisionK253834 · Product code: **HJO** · Ophthalmic
Source: <https://www.510kdatabase.net/k253834/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biomicroscope, Slit-lamp, Ac-powered (HJO)
Date received	Dec 1, 2025
Decision date	Mar 18, 2026
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Carl Zeiss Vision GmbH
Location	Aalen, DE
Contact	Oliver Jucha-Schade
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Carl Zeiss Vision, Inc.
Contact	Jahmal Cannon

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

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