FDA 510(k) Premarket Notification

K251848 Pentacam® Cornea OCT

CLEARED

Mar 13, 2026
270 days to decision

K251848 · Product code: **MXK** · Ophthalmic
Source: https://www.510kdatabase.net/k251848/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Analysis, Anterior Segment (MXK)
Date received	Jun 16, 2025
Decision date	Mar 13, 2026
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Oculus Optikger?te GmbH**
Location	Wetzlar, DE
Contact	Agata Kufel
510(k) history	2 submissions · 2 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells**
Contact	Randy Prebula

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