

K251848 Pentacam® Cornea OCTMar 13, 2026
270 days to decisionK251848 · 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

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