

**K201724 Pentacam AXL Wave**Oct 21, 2020  
120 days to decisionK201724 · Product code: **MXK** · Ophthalmic  
Source: <https://www.510kdatabase.net/k201724/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Analysis, Anterior Segment (MXK)
Date received	Jun 23, 2020
Decision date	Oct 21, 2020
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Oculus Optikgerate GmbH</b>
Location	Woodinville, WA, US
Contact	Eckhard Loh
510(k) history	6 submissions · 6 cleared · 2003-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Randy Prebula

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

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