

**K202989 Myopia Master**Jul 14, 2021  
287 days to decisionK202989 · Product code: **MXK** · Ophthalmic  
Source: <https://www.510kdatabase.net/k202989/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Analysis, Anterior Segment (MXK)
Date received	Sep 30, 2020
Decision date	Jul 14, 2021
Days to decision	287 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Oculus Optikger?te GmbH</b>
Location	Wetzlar, DE
Contact	Eckhard Loh
510(k) history	2 submissions · 2 cleared · 2021-2026

**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

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