

**K211868 MYAH**Mar 1, 2022  
258 days to decisionK211868 · Product code: **MXK** · Ophthalmic  
Source: <https://www.510kdatabase.net/k211868/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Analysis, Anterior Segment (MXK)
Date received	Jun 16, 2021
Decision date	Mar 1, 2022
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Visia Imaging S.R.L.</b>
Location	Ormond Beach, FL, US
Contact	Alessia Magnanini
510(k) history	4 submissions · 4 cleared · 2014-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>THEMA S.r.l.</b>
Contact	Marisa Testa

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211868/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 27, 2026