

K222933 MYAHJun 29, 2023
276 days to decisionK222933 · Product code: **MXK** · Ophthalmic
Source: <https://www.510kdatabase.net/k222933/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Analysis, Anterior Segment (MXK)
Date received	Sep 26, 2022
Decision date	Jun 29, 2023
Days to decision	276 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	THEMA S.r.l.
Contact	Marisa Testa

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

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