FDA 510(k) Premarket Notification

K211868 MYAH

CLEARED

Mar 1, 2022
258 days to decision

K211868 · Product code: **MXK** · Ophthalmic
Source: https://www.510kdatabase.net/k211868/

SUBMISSION DETAILS

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

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