FDA 510(k) Premarket Notification

K243504 MAIA (AHMACME001)

CLEARED

Mar 17, 2025
125 days to decision

K243504 · Product code: **MYC** · Ophthalmic
Source: https://www.510kdatabase.net/k243504/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Laser, Scanning (MYC)
Date received	Nov 12, 2024
Decision date	Mar 17, 2025
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Centervue S.P.A.**
Location	Padova, IT
Contact	Luca Scienza
510(k) history	13 submissions · 13 cleared · 2010-2025