

**K243504 MAIA (AHMACME001)**Mar 17, 2025  
125 days to decisionK243504 · Product code: **MYC** · Ophthalmic  
Source: <https://www.510kdatabase.net/k243504/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243504/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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