

K243831 Rayvolve LNMar 26, 2025
103 days to decisionK243831 · Product code: **MYN** · Radiology
Source: <https://www.510kdatabase.net/k243831/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Dec 13, 2024
Decision date	Mar 26, 2025
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	AZmed
Location	Paris, FR
Contact	Christelle Baille
510(k) history	2 submissions · 2 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243831/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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