FDA 510(k) Premarket Notification

K243831 Rayvolve LN

CLEARED

Mar 26, 2025
103 days to decision

K243831 · 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