FDA 510(k) Premarket Notification

K243808 Rayvolve PTX-PE

CLEARED

Mar 21, 2025
100 days to decision

K243808 · Product code: **QFM** · Radiology
Source: https://www.510kdatabase.net/k243808/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Dec 11, 2024
Decision date	Mar 21, 2025
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**AZmed**
Location	Paris, FR
Contact	Anthony Joseph
510(k) history	2 submissions · 2 cleared · 2025-2025