

**K243808 Rayvolve PTX-PE**Mar 21, 2025  
100 days to decisionK243808 · Product code: **QFM** · Radiology  
Source: <https://www.510kdatabase.net/k243808/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243808/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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