

K251934 qXR-DetectJan 16, 2026
206 days to decisionK251934 · Product code: **MYN** · Radiology
Source: <https://www.510kdatabase.net/k251934/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Jun 24, 2025
Decision date	Jan 16, 2026
Days to decision	206 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Qure.AI Technologies
Location	Mumbai, IN
Contact	Sri Anusha Matta
510(k) history	9 submissions · 9 cleared · 2020-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251934/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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