FDA 510(k) Premarket Notification

K251934 qXR-Detect

CLEARED

Jan 16, 2026
206 days to decision

K251934 · 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