

K213941 Annalise Enterprise CXR Triage PneumothoraxFeb 24, 2022
70 days to decisionK213941 · Product code: **QFM** · Radiology
Source: <https://www.510kdatabase.net/k213941/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Dec 16, 2021
Decision date	Feb 24, 2022
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Annalise-Ai
Location	Sydney, AU
Contact	Eric Qin
510(k) history	2 submissions · 2 cleared · 2022-2025

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