

K250831 Annalise EnterpriseApr 23, 2025
35 days to decisionK250831 · Product code: **QFM** · Radiology
Source: <https://www.510kdatabase.net/k250831/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Mar 19, 2025
Decision date	Apr 23, 2025
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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