

K253818 Annalise EnterpriseMar 3, 2026
95 days to decisionK253818 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k253818/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Nov 28, 2025
Decision date	Mar 3, 2026
Days to decision	95 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Harrison-AI Medical Pty, Ltd.
Location	Sydney, AU
Contact	Haylee Bosshard
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Harrison-AI Medical Pty Ltd (formerly Annalise-AI Pty Ltd)
Contact	Haylee Bosshard

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253818/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026