

K231767 Annalise Enterprise CTB Triage TraumaSep 22, 2023
98 days to decisionK231767 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k231767/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Jun 16, 2023
Decision date	Sep 22, 2023
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Annalise-Ai Pty , Ltd.
Location	Sydney, AU
Contact	Haylee Bosshard
510(k) history	6 submissions · 6 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231767/> 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 26, 2026