

K231384 Annalise Enterprise CTB Triage Trauma

Sep 22, 2023
133 days to decision

K231384 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k231384/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	May 12, 2023
Decision date	Sep 22, 2023
Days to decision	133 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

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Device record: <https://www.510kdatabase.net/k231384/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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