

K252366 a2z-Unified-TriageNov 24, 2025
117 days to decisionK252366 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k252366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Jul 30, 2025
Decision date	Nov 24, 2025
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	A2z Radiology Ai, Inc.
Location	Boston, MA, US
Contact	Samir Rajpurkar
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252366/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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