

K253265 BriefCase-TriageNov 6, 2025
38 days to decisionK253265 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k253265/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Sep 29, 2025
Decision date	Nov 6, 2025
Days to decision	38 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Aidoc Medical , Ltd.
Location	Tel Aviv, IL
Contact	Amalia Schreier
Website	https://www.aidoc.com
510(k) history	34 submissions · 34 cleared · 2018-2026

Aidoc Medical, Ltd. is a healthcare AI company based in Tel Aviv, Israel. The company develops clinical AI solutions for medical imaging and diagnostic workflows. Aidoc has received FDA 510(k) clearances from total submissions since 2018. The company specializes exclusively in Radiology devices, with a dominant portfolio of FDA-cleared algorithms. The latest clearance was in 2026, confirming active regulatory engagement. The company's product portfolio includes the BriefCase platform, featuring triage and quantification algorithms for CT imaging. Notable cleared devices a...