

## K253578 BriefCase-Triage: CARE Multi-Triage CT for Pneumothorax

Feb 26, 2026  
101 days to decisionK253578 · Product code: **QAS** · Radiology  
Source: <https://www.510kdatabase.net/k253578/>

### SUBMISSION DETAILS

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Nov 17, 2025
Decision date	Feb 26, 2026
Days to decision	101 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Pericardial effusion; Large aortic aneurysm; Shoulder fracture or dislocation device

### APPLICANT

---

Company	<b>Aidoc Medical , Ltd.</b>
Location	Tel Aviv, IL
Contact	Amalia Schreier
Website	<a href="https://www.aidoc.com">https://www.aidoc.com</a>
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...