

K180647 BriefCase

Aug 1, 2018
142 days to decision

K180647 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k180647/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Mar 12, 2018
Decision date	Aug 1, 2018
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aidoc Medical , Ltd.
Location	Tel Aviv, IL
Contact	Nimrod Epstein
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...