

K214043 BriefCaseMar 14, 2022
81 days to decisionK214043 · Product code: **QFM** · Radiology
Source: <https://www.510kdatabase.net/k214043/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Dec 23, 2021
Decision date	Mar 14, 2022
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	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...

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	John J. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)
