

**K222692 BriefCase**Dec 5, 2022  
90 days to decisionK222692 · Product code: **QFM** · Radiology  
Source: <https://www.510kdatabase.net/k222692/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Sep 6, 2022
Decision date	Dec 5, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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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...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
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)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k222692/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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