

K221314 BriefCase

Jun 3, 2022
29 days to decision

K221314 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k221314/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Radiological Computer-assisted Triage And Notification Software (QAS) |
| Date received | May 5, 2022 |
| Decision date | Jun 3, 2022 |
| Days to decision | 29 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

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|-----------------|-----------------------------|
| 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)
