FDA 510(k) Premarket Notification

K193298 BriefCase

CLEARED

Jun 19, 2020
205 days to decision

K193298 · Product code: **QAS** · Radiology
Source: https://www.510kdatabase.net/k193298/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Nov 27, 2019
Decision date	Jun 19, 2020
Days to decision	205 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	35 submissions · 35 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