

K234141 AISAP Cardio V1.0Aug 1, 2024
216 days to decisionK234141 · Product code: **POK** · Radiology
Source: <https://www.510kdatabase.net/k234141/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Dec 29, 2023
Decision date	Aug 1, 2024
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aisap
Location	Ramat Gan, IL
Contact	Robert Klempfner
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells
Contact	John Smith

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k234141/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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