

K233342 CINA-ASPECTSMar 15, 2024
168 days to decisionK233342 · Product code: **POK** · Radiology
Source: <https://www.510kdatabase.net/k233342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Sep 29, 2023
Decision date	Mar 15, 2024
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avicenna.Ai
Location	La Ciotat, FR
Contact	Stephane Berger
510(k) history	7 submissions · 7 cleared · 2020-2024

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

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