

K240612 CINA-VCFMay 31, 2024
87 days to decisionK240612 · Product code: **QFM** · Radiology
Source: <https://www.510kdatabase.net/k240612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Prioritization Software For Lesions (QFM)
Date received	Mar 5, 2024
Decision date	May 31, 2024
Days to decision	87 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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