

K252084 AI4CMR v2.0Feb 11, 2026
224 days to decisionK252084 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k252084/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 2, 2025
Decision date	Feb 11, 2026
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ai4medimaging Medical Solutions S.A.
Location	Braga, PT
Contact	Carla Almeida
510(k) history	2 submissions · 2 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	Meditec Consulting GmbH
Contact	Sandra Soniec

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

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