

K252548 AI-Rad Companion Organs RTApr 10, 2026
240 days to decisionK252548 · Product code: **QKB** · Radiology
Source: <https://www.510kdatabase.net/k252548/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Image Processing Software For Radiation Therapy (QKB)
Date received	Aug 13, 2025
Decision date	Apr 10, 2026
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare GmbH
Location	Erlangen, DE
Contact	Kira Morales
510(k) history	30 submissions · 30 cleared · 2016-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252548/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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