

K252608 AI-Rad Companion Prostate MRSep 9, 2025
22 days to decisionK252608 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k252608/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 18, 2025
Decision date	Sep 9, 2025
Days to decision	22 days
Third-party review	Yes
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

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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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