

K253495 syngo.MR Applications (VB80)Nov 20, 2025
23 days to decisionK253495 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k253495/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 28, 2025
Decision date	Nov 20, 2025
Days to decision	23 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthineers AG
Location	Forchheim, DE
Contact	Vijay Ramadas
Website	http://www.siemens.de/healthcare
510(k) history	3 submissions · 3 cleared · 2025-2026

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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