

**K241770 Prostate MR AI (VA10A)**Mar 5, 2025  
258 days to decisionK241770 · Product code: **QDQ** · Radiology  
Source: <https://www.510kdatabase.net/k241770/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Lesions Suspicious For Cancer (QDQ)
Date received	Jun 20, 2024
Decision date	Mar 5, 2025
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare GmbH</b>
Location	Erlangen, DE
Contact	Abhineet Johri
510(k) history	30 submissions · 30 cleared · 2016-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241770/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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