

K193283 AI-Rad Companion Prostate MRJul 30, 2020
246 days to decisionK193283 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k193283/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 27, 2019
Decision date	Jul 30, 2020
Days to decision	246 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Medical Solutions USA, Inc.
Location	Hoffman Estates, IL, US
Contact	Lauren Bentley
510(k) history	779 submissions · 779 cleared · 1980-2026

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