

**K183268 AI-Rad Companion (Cardiovascular)**Sep 10, 2019  
291 days to decisionK183268 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k183268/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 23, 2018
Decision date	Sep 10, 2019
Days to decision	291 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Medical Solutions USA, Inc.</b>
Location	Hoffman Estates, IL, US
Contact	Kimberly Rendon
510(k) history	779 submissions · 779 cleared · 1980-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183268/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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