

K213713 AI-Rad Companion (Pulmonary)Aug 11, 2022
260 days to decisionK213713 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k213713/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 24, 2021
Decision date	Aug 11, 2022
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare GmbH
Location	Erlangen, DE
Contact	Lauren Bentley
510(k) history	30 submissions · 30 cleared · 2016-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213713/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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