FDA 510(k) Premarket Notification

K213713 AI-Rad Companion (Pulmonary)

CLEARED

Aug 11, 2022
260 days to decision

K213713 · 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