

K212494 Lung Image AnalysisSep 2, 2021
24 days to decisionK212494 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k212494/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Aug 9, 2021
Decision date	Sep 2, 2021
Days to decision	24 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pulmonx Corporation
Location	Redwood Citry, CA, US
Contact	Terry Solomon
510(k) history	4 submissions · 4 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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