

**K193293 XV Lung Ventilation Analysis Software**May 14, 2020  
169 days to decisionK193293 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k193293/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 27, 2019
Decision date	May 14, 2020
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>4Dx Limited</b>
Location	Melbourne, AU
Contact	Terrence Thiel
510(k) history	1 submissions · 1 cleared · 2020-2020

**CLINICAL EVIDENCE - NCT02735746**

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**Novel Lung Imaging in Adults Undergoing Radiation Therapy to Assess for Radiation Pneumonitis**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	60 patients (estimated)
Study sites	1 site
Condition studied	Lung Cancer; Breast Cancer; Mediastinum Lesion; Radiation Pneumonitis
Study type	Observational
Completion date	Jun 6, 2025
Sponsor	Cedars-Sinai Medical Center (Other)

**Primary outcome**

A Pearson correlation of >0.579 between peak expiratory flow as measured by HFFLI analysis of cinefluorograph compared with 4D planning CT

**Secondary outcome**

Forced expiratory volume 1 (FEV1)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT02735746](https://clinicaltrials.gov/study/NCT02735746)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k193293/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov/)), ClinicalTrials.gov (U.S. National Library of Medicine). 510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov/). - Generated June 28, 2026