FDA 510(k) Premarket Notification

K250370 SCENARIA View Phase 5.0

CLEARED

May 20, 2025
99 days to decision

K250370 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k250370/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Feb 10, 2025
Decision date	May 20, 2025
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Corporation**
Location	Ashigara Kami-Gun, JP
Contact	Chaitrali Kulkarni
510(k) history	62 submissions · 62 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	**FUJIFILM Healthcare Americas Corporation**
Contact	Chaitrali Kulkarni

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k250370/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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