FDA 510(k) Premarket Notification

K231574 Scenaria View 4.2

CLEARED

Oct 12, 2023
134 days to decision

K231574 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k231574/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	May 31, 2023
Decision date	Oct 12, 2023
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Healthcare Americas Corporation**
Location	Lexington, MA, US
Contact	Chaitrali Kulkarni
510(k) history	12 submissions · 12 cleared · 2023-2025