FDA 510(k) Premarket Notification

K213829 SCENARIA View

CLEARED

May 23, 2022
166 days to decision

K213829 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k213829/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Dec 8, 2021
Decision date	May 23, 2022
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Healthcare Corporation**
Location	Kashiwa-Shi, JP
Contact	Randy Vader
510(k) history	6 submissions · 6 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	**FUJIFILM Healthcare Americas Corporation**
Contact	Dennis Domoracki

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