

K250970 MarieJul 25, 2025
116 days to decisionK250970 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k250970/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Mar 31, 2025
Decision date	Jul 25, 2025
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Leo Cancer Care
Location	Middleton, WI, US
Contact	Nickie Power
510(k) history	2 submissions · 2 cleared · 2024-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250970/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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