

K253686 True Definition DLMar 23, 2026
122 days to decisionK253686 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k253686/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 21, 2025
Decision date	Mar 23, 2026
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ge Healthcare Japan Corporation
Location	Hino-Shi, Tokyo, JP
Contact	Yonghui Han
510(k) history	10 submissions · 10 cleared · 2011-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253686/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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