

K251484 CT:VQAug 28, 2025
106 days to decisionK251484 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k251484/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	May 14, 2025
Decision date	Aug 28, 2025
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	4Dmedical Limited
Location	Carlton, AU
Contact	Theresa Poole
510(k) history	2 submissions · 2 cleared · 2023-2025

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