

K230112 CAC SoftwareJun 13, 2023
147 days to decisionK230112 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k230112/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jan 17, 2023
Decision date	Jun 13, 2023
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Imbio, Inc.
Location	Minneapolis, MN, US
Contact	Kay Sisavath
510(k) history	3 submissions · 3 cleared · 2023-2024

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