

K213725 CardIQ SuiteMar 11, 2022
105 days to decisionK213725 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k213725/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 26, 2021
Decision date	Mar 11, 2022
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	GE Medical Systems SCS
Location	Buc Cedex, FR
Contact	Yonghui Han
510(k) history	37 submissions · 37 cleared · 2008-2026

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