

K193289 FastStroke, CT Perfusion 4DNov 12, 2020
351 days to decisionK193289 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k193289/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 27, 2019
Decision date	Nov 12, 2020
Days to decision	351 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	Elizabeth Mathew
510(k) history	37 submissions · 37 cleared · 2008-2026

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