

**K233583 FCT iSTREAM Phase 1**Apr 26, 2024  
171 days to decisionK233583 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k233583/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 7, 2023
Decision date	Apr 26, 2024
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujifilm Healthcare Americas Corporation</b>
Location	Lexington, MA, US
Contact	Chaitrali Kulkarni
510(k) history	12 submissions · 12 cleared · 2023-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233583/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026