

**K163281 FastStroke**Jan 26, 2017  
66 days to decisionK163281 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k163281/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 21, 2016
Decision date	Jan 26, 2017
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gef Medical Systems Scs</b>
Location	Buc, FR
Contact	Kristine Schraufnagel
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163281/> 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 16, 2026