

**K143401 SOMATOM Definition Edge**Apr 6, 2015  
129 days to decisionK143401 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k143401/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 28, 2014
Decision date	Apr 6, 2015
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Medical Solutions USA, Inc.</b>
Location	Hoffman Estates, IL, US
Contact	KIMBERLY MANGUM
510(k) history	778 submissions · 778 cleared · 1980-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143401/> 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 15, 2026