

**K131433 ISYS 1 (U.S),ACCESSORY, NON-STERILE**Mar 11, 2014  
298 days to decisionK131433 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k131433/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	May 17, 2013
Decision date	Mar 11, 2014
Days to decision	298 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Isys Medizintechnik GmbH</b>
Location	Stamford, CT, US
Contact	CORNELIA DAMSKY
510(k) history	3 submissions · 3 cleared · 2014-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131433/> 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 26, 2026