

**K122241 IMAGEN3D**Oct 24, 2012  
89 days to decisionK122241 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k122241/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Jul 27, 2012
Decision date	Oct 24, 2012
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardiovascular Imaging Technologies</b>
Location	Lenexa, KS, US
Contact	MELANIE HASEK
510(k) history	4 submissions · 4 cleared · 2012-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122241/> 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 June 15, 2026