

**K172609 CSMC Cardiac Suite**Nov 3, 2017  
64 days to decisionK172609 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k172609/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Aug 31, 2017
Decision date	Nov 3, 2017
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cedars-Sinai Medical Center</b>
Location	Jacksonville, FL, US
Contact	Geoff Pollard
Website	<a href="http://www.cedars-sinai.edu/">http://www.cedars-sinai.edu/</a>
510(k) history	5 submissions · 5 cleared · 2011-2017

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172609/> 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