

**K152733 FFRct**Jan 13, 2016  
113 days to decisionK152733 · Product code: **PJA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k152733/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coronary Vascular Physiologic Simulation Software (PJA)
Date received	Sep 22, 2015
Decision date	Jan 13, 2016
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>HeartFlow, Inc.</b>
Location	Redwood City, CA, US
Contact	WINDI HARY
510(k) history	7 submissions · 7 cleared · 2016-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152733/> 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