

**K110493 TANDEMHEART PUMP**Sep 20, 2011  
210 days to decisionK110493 · Product code: **KFM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k110493/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Feb 22, 2011
Decision date	Sep 20, 2011
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardiacassist, Inc.</b>
Location	Pittsburgh, PA, US
Contact	ROBERT BOLLINGER
510(k) history	21 submissions · 21 cleared · 2000-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110493/> 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 18, 2026