

**K120543 TANDEMHEART FEMORAL ARTERIAL CANNULA SET**May 30, 2012  
97 days to decisionK120543 · Product code: **DWF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k120543/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Feb 23, 2012
Decision date	May 30, 2012
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardiacassist, Inc.</b>
Location	Pittsburgh, PA, US
Contact	KATIE DILLON
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/k120543/> 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 14, 2026