

K082425 TANDEMHEART TRANSSEPTAL CANNULA- EF 72Sep 18, 2008
27 days to decisionK082425 · Product code: **DWF** · CardiovascularSource: <https://www.510kdatabase.net/k082425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Aug 22, 2008
Decision date	Sep 18, 2008
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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