

**K961594 BETTER-VENTER**Sep 5, 1996  
134 days to decisionK961594 · Product code: **DWF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k961594/>**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	Apr 24, 1996
Decision date	Sep 5, 1996
Days to decision	134 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Circulatory Technology, Inc.</b>
Location	Oyster Bay, NY, US
Contact	YEHUDA TAMARI
510(k) history	9 submissions · 9 cleared · 1994-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k961594/> 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 7, 2026