

**K936003 AFFINITY CVR**Jun 20, 1994  
186 days to decisionK936003 · Product code: **DTN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k936003/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Dec 16, 1993
Decision date	Jun 20, 1994
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Avecor Cardiovascular, Inc.</b>
Location	Plymouth, MN, US
Contact	DENNIS E STEGER
510(k) history	9 submissions · 8 cleared · 1993-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k936003/> 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 28, 2026