

**K990396 T-ANASTAFLO**Oct 1, 1999  
234 days to decisionK990396 · Product code: **DWF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k990396/>**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 9, 1999
Decision date	Oct 1, 1999
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Edwards Lifesciences Research Medical</b>
Location	Midvale, UT, US
Contact	JOHN W SMITH
510(k) history	6 submissions · 6 cleared · 1998-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k990396/> 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