

**K880180 STATFLO**Mar 22, 1988  
69 days to decisionK880180 · Product code: **DWF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k880180/>**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	Jan 13, 1988
Decision date	Mar 22, 1988
Days to decision	69 days
Third-party review	No

**APPLICANT**

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Company	<b>Imodex, Inc.</b>
Location	St. Clair Shores, MI, US
Contact	SHELDON H DAVIS
510(k) history	2 submissions · 2 cleared · 1986-1988

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k880180/>, 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 July 7, 2026