

**K860497 CAROTID BALLOON SHUNT**May 28, 1986  
107 days to decisionK860497 · Product code: **DWF** · CardiovascularSource: <https://www.510kdatabase.net/k860497/>**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 10, 1986
Decision date	May 28, 1986
Days to decision	107 days
Third-party review	No

**APPLICANT**

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Company	<b>Imodex, Inc.</b>
Location	St. Clair Shores, MI, US
Contact	SHELDON 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/k860497/>; 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