

**K822350 SWAN-GANZ FLOW-DIRECTED THERMODIL. CATH**Aug 24, 1982  
18 days to decisionK822350 · Product code: **DYG** · CardiovascularSource: <https://www.510kdatabase.net/k822350/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Flow Directed (DYG)
Date received	Aug 6, 1982
Decision date	Aug 24, 1982
Days to decision	18 days
Third-party review	No

**APPLICANT**

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Company	<b>American Edwards Laboratories</b>
Location	Walker, MI, US
510(k) history	89 submissions · 88 cleared · 1980-1987

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k822350/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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