

K803058 SWAN-GANZ FLOW-DIRECTED MULTIPUR. CATH.Jan 16, 1981
45 days to decisionK803058 · Product code: **LDF** · Cardiovascular
Source: <https://www.510kdatabase.net/k803058/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Pacemaker, Temporary (LDF)
Date received	Dec 2, 1980
Decision date	Jan 16, 1981
Days to decision	45 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k803058/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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