

K891000 MODIFIED EXTERNAL PADMay 19, 1989
81 days to decisionK891000 · Product code: **DWS** · CardiovascularSource: <https://www.510kdatabase.net/k891000/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instruments, Surgical, Cardiovascular (DWS)
Date received	Feb 27, 1989
Decision date	May 19, 1989
Days to decision	81 days
Third-party review	No

APPLICANT

Company	Instromedix, Inc.
Location	Mchenry, IL, US
Contact	SEMLER, M.D.
510(k) history	32 submissions · 32 cleared · 1977-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k891000/>, Data sourced from FDA 510(k) public records (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. - Generated July 6, 2026