FDA 510(k) Premarket Notification

K891000 MODIFIED EXTERNAL PAD

CLEARED

May 19, 1989
81 days to decision

K891000 · Product code: **DWS** · Cardiovascular
Source: 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