FDA 510(k) Premarket Notification

K892798 9 FR PERCUTAN DOUBLE LUMEN INTRA-AORTIC BALLOON

CLEARED

Sep 20, 1989
156 days to decision

K892798 · Product code: **DSP** · Cardiovascular
Source: https://www.510kdatabase.net/k892798/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Apr 17, 1989
Decision date	Sep 20, 1989
Days to decision	156 days
Third-party review	No

APPLICANT

Company	**Kontron Instruments, Inc.**
Location	Mchenry, IL, US
Contact	DAVID CROMWICK
510(k) history	57 submissions · 57 cleared · 1981-1993