FDA 510(k) Premarket Notification

K903344 9.5 FR PERCUTANEOUS DB LUMEN 40CC FLEXI-CATH (TM)

CLEARED

Jan 15, 1991
174 days to decision

K903344 · Product code: **DSP** · Cardiovascular
Source: https://www.510kdatabase.net/k903344/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Jul 25, 1990
Decision date	Jan 15, 1991
Days to decision	174 days
Third-party review	No

APPLICANT

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