FDA 510(k) Premarket Notification

K820166 ADAPTATION OF KANTRON 40 CC. PDLIAB

CLEARED

Apr 29, 1982
98 days to decision

K820166 · Product code: **DSP** · Cardiovascular
Source: https://www.510kdatabase.net/k820166/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Jan 21, 1982
Decision date	Apr 29, 1982
Days to decision	98 days
Third-party review	No

APPLICANT

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