FDA 510(k) Premarket Notification

K840037 MODIFIED SMEC PERCUTANEOUS INTRA-AORTIC

CLEARED

Feb 1, 1985
393 days to decision

K840037 · Product code: **DSP** · Cardiovascular
Source: https://www.510kdatabase.net/k840037/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Jan 5, 1984
Decision date	Feb 1, 1985
Days to decision	393 days
Third-party review	No

APPLICANT

Company	**Smec, Inc.**
Location	Mchenry, IL, US
510(k) history	7 submissions · 7 cleared · 1980-1985