

K840037 MODIFIED SMEC PERCUTANEOUS INTRA-AORTICFeb 1, 1985
393 days to decisionK840037 · Product code: **DSP** · CardiovascularSource: <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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k840037/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 8, 2026