

K823739 INTRA-AORTIC BALLOON SYSTEMFeb 18, 1983
67 days to decisionK823739 · Product code: **DSP** · CardiovascularSource: <https://www.510kdatabase.net/k823739/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Dec 13, 1982
Decision date	Feb 18, 1983
Days to decision	67 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k823739/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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