

K850627 SPACELABS-GENERAL SYSTEM LINKMay 28, 1985
98 days to decisionK850627 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k850627/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Feb 19, 1985
Decision date	May 28, 1985
Days to decision	98 days
Third-party review	No

APPLICANT

Company	Spacelabs, Inc.
Location	Mchenry, IL, US
Contact	ALLEN M HANS
Website	https://www.spacelabshealthcare.com
510(k) history	46 submissions · 46 cleared · 1976-1996

Spacelabs, Inc. is a medical device company based in McHenry, US. The company specializes in patient monitoring and diagnostic cardiology solutions. Spacelabs received FDA 510(k) clearances from total submissions. The company's regulatory activity spans from 1976 to 1996, with Cardiovascular devices representing the dominant focus of its portfolio. This historical record reflects the company's early contributions to cardiac monitoring and anesthesiology device development. Notable cleared devices include multigas analyzers, capnograph modules, patient care management syst...

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Device record: <https://www.510kdatabase.net/k850627/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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