

K913038 SPACELAB MODEL 90845 PCMS MULTIDISCLOSURE STATIONOct 4, 1991
87 days to decisionK913038 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k913038/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Jul 9, 1991
Decision date	Oct 4, 1991
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Spacelabs, Inc.
Location	Mchenry, IL, US
Contact	RAYMOND W.GIFFORD
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...