

**K951605 SPACELABS MEDICAL CASEMASTER INFORMATION
MANAGEMENT SYSTEM**Jul 14, 1995
98 days to decisionK951605 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k951605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Apr 7, 1995
Decision date	Jul 14, 1995
Days to decision	98 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Spacelabs, Inc.
Location	Mchenry, IL, US
Contact	RUSS GARRISON
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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k951605/> 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 May 25, 2026