

K923788 SPACE LABS MODEL 90560Dec 6, 1993
496 days to decisionK923788 · Product code: **LOS** · Cardiovascular
Source: <https://www.510kdatabase.net/k923788/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Jul 28, 1992
Decision date	Dec 6, 1993
Days to decision	496 days
Third-party review	No
Summary / Statement	Summary

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...
