

K896427 SPACELABS'S MODEL 90514, MULTIGAS ANALYZERJan 24, 1990
77 days to decisionK896427 · Product code: CCL · Anesthesiology
Source: <https://www.510kdatabase.net/k896427/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Oxygen, Gaseous-phase (CCL)
Date received	Nov 8, 1989
Decision date	Jan 24, 1990
Days to decision	77 days
Third-party review	No

APPLICANT

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