FDA 510(k) Premarket Notification

K811540 SPACELABS' SYSTEM AUTORECORDER

CLEARED

Aug 13, 1981
73 days to decision

K811540 · Product code: **DSF** · Cardiovascular
Source: https://www.510kdatabase.net/k811540/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Paper Chart (DSF)
Date received	Jun 1, 1981
Decision date	Aug 13, 1981
Days to decision	73 days
Third-party review	No

APPLICANT

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