

K842640 SPACELABS ICR ARRHYTHMIA MASTER I HOLTEROct 4, 1984
86 days to decisionK842640 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k842640/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Jul 10, 1984
Decision date	Oct 4, 1984
Days to decision	86 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...
