FDA 510(k) Premarket Notification

K864505 SPACELABS ARRHYTHMIA NET (TM) LEVEL 2

CLEARED

Nov 24, 1986
10 days to decision

K864505 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k864505/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Nov 14, 1986
Decision date	Nov 24, 1986
Days to decision	10 days
Third-party review	No

APPLICANT

Company	**Spacelabs, Inc.**
Location	Mchenry, IL, US
Contact	HANS, P.E.
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...