FDA 510(k) Premarket Notification

K760884 MICRO-COMPUTER ARRHYTHONIA SYSTEM

CLEARED

Dec 9, 1976
48 days to decision

K760884 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k760884/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Oct 22, 1976
Decision date	Dec 9, 1976
Days to decision	48 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...