

K830306 HEARTRATE PLUS ECG CARDULE #1918Mar 17, 1983
45 days to decisionK830306 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k830306/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Jan 31, 1983
Decision date	Mar 17, 1983
Days to decision	45 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...

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