

K962970 SPACELABS MEDICAL 12-LEAD DIAGNOSTIC ECG ANALYSIS OPTION

Mar 25, 1997
237 days to decision

K962970 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k962970/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Jul 31, 1996
Decision date	Mar 25, 1997
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spacelabs Medical, Inc.
Location	Hamden, CT, US
Contact	RUSS GARRISON
510(k) history	35 submissions · 34 cleared · 1993-2012

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Device record: <https://www.510kdatabase.net/k962970/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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