

K832693 ARRHYTHMIA III CARDULE #1919Nov 7, 1983
89 days to decisionK832693 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k832693/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Detector And Alarm, Arrhythmia (DSI) |
| Date received | Aug 10, 1983 |
| Decision date | Nov 7, 1983 |
| Days to decision | 89 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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