

K842616 SPACELABS ALPHA PC PATIENT COMPUTEROct 18, 1984
105 days to decisionK842616 · Product code: **DSI** · Cardiovascular
Source: <https://www.510kdatabase.net/k842616/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Detector And Alarm, Arrhythmia (DSI) |
| Date received | Jul 5, 1984 |
| Decision date | Oct 18, 1984 |
| Days to decision | 105 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Spacelabs, Inc. |
| Location | Mchenry, IL, US |
| Contact | WILLIAM M FRANK |
| 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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k842616/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026