

**K834597 ALPHA MASS STORAGE CARDULE 1895**Apr 17, 1984  
109 days to decisionK834597 · Product code: **DSI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k834597/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Dec 30, 1983
Decision date	Apr 17, 1984
Days to decision	109 days
Third-party review	No

**APPLICANT**

---

Company	<b>Spacelabs, Inc.</b>
Location	Mchenry, IL, US
Website	<a href="https://www.spacelabshealthcare.com">https://www.spacelabshealthcare.com</a>
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](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k834597/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026