FDA 510(k) Premarket Notification

# K791776 ARRHYTHMIA II EDITOR

**CLEARED**

Oct 2, 1979
22 days to decision

K791776 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k791776/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Computer, Diagnostic, Programmable (DQK) |
| Date received | Sep 10, 1979 |
| Decision date | Oct 2, 1979 |
| Days to decision | 22 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...