

K761244 SERIES 700 PATIENT MONITORSDec 23, 1976
10 days to decisionK761244 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k761244/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Dec 13, 1976
Decision date	Dec 23, 1976
Days to decision	10 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...
