FDA 510(k) Premarket Notification

K760120 PULSE CARDULE (MODEL 1859/1860 ECG)

CLEARED

Jul 20, 1976
22 days to decision

K760120 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k760120/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Jun 28, 1976
Decision date	Jul 20, 1976
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...