FDA 510(k) Premarket Notification

K904318 LOCAL REPORT GENERATOR

CLEARED

Dec 18, 1990
89 days to decision

K904318 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k904318/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Sep 20, 1990
Decision date	Dec 18, 1990
Days to decision	89 days
Third-party review	No

APPLICANT

Company	**Spacelabs, Inc.**
Location	Mchenry, IL, US
Contact	RAYMOND W GIFFORD
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...