FDA 510(k) Premarket Notification

K901209 MODEL 90489 PULSE OXIMETER MODULE

CLEARED

Apr 30, 1990
47 days to decision

K901209 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k901209/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Mar 14, 1990
Decision date	Apr 30, 1990
Days to decision	47 days
Third-party review	No

APPLICANT

Company	**Spacelabs, Inc.**
Location	Mchenry, IL, US
Contact	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...