FDA 510(k) Premarket Notification

K935220 CORE PREVENT MATTRESS MODIFICATION

CLEARED

Nov 29, 1993
48 days to decision

K935220 · Product code: **FMW** · General Hospital
Source: https://www.510kdatabase.net/k935220/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Mattress (medical Purposes) (FMW)
Date received	Oct 12, 1993
Decision date	Nov 29, 1993
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Paladin Medical, Inc.**
Location	Stillwater, MN, US
Contact	ELAINE DUNCAN
510(k) history	14 submissions · 14 cleared · 1992-1999