FDA 510(k) Premarket Notification

K931266 BATTERY PACK #1012NC

CLEARED

Feb 3, 1994
332 days to decision

K931266 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k931266/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Mar 8, 1993
Decision date	Feb 3, 1994
Days to decision	332 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Portable Power Systems, Inc.**
Location	Castle Rock, CO, US
Contact	NORMAN PREMO
510(k) history	18 submissions · 18 cleared · 1992-1997