FDA 510(k) Premarket Notification

K931716 BATTERY PACK 1017LA

CLEARED

Feb 7, 1994
307 days to decision

K931716 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k931716/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Apr 6, 1993
Decision date	Feb 7, 1994
Days to decision	307 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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