FDA 510(k) Premarket Notification

K082937 LIFEPAK 15 MONITOR/DEFIBRILLATOR

CLEARED

Mar 11, 2009
161 days to decision

K082937 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k082937/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Oct 1, 2008
Decision date	Mar 11, 2009
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Physio-Control, Inc.**
Location	Redmond, WA, US
Contact	TERESA DAVIDSON
510(k) history	14 submissions · 14 cleared · 1984-2025