FDA 510(k) Premarket Notification

K063510 LIFEPAK 12 DEFIBRILLATOR/MONITOR

CLEARED

Jan 26, 2007
67 days to decision

K063510 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k063510/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Nov 20, 2006
Decision date	Jan 26, 2007
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Emergency Response Systems, Inc.**
Location	Redmond, WA, US
Contact	MICHELLE ACKERMANN
510(k) history	6 submissions · 6 cleared · 2004-2007