FDA 510(k) Premarket Notification

CLEARED

K130454 LIFEPAK 20 DEFIBRILLATOR/MONITOR, LIFEPAK 20E DEFIBRILLATOR/MONITOR

Aug 21, 2013
180 days to decision

K130454 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k130454/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Feb 22, 2013
Decision date	Aug 21, 2013
Days to decision	180 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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