FDA 510(k) Premarket Notification

K122758 POWERHEART G5 AED

CLEARED

Feb 12, 2014
520 days to decision

K122758 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k122758/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Sep 10, 2012
Decision date	Feb 12, 2014
Days to decision	520 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiac Science Corporation**
Location	Bothell, WA, US
Contact	KATHLEEN ROBERTS
510(k) history	10 submissions · 10 cleared · 2006-2015