FDA 510(k) Premarket Notification

K091943 POWERHEART AED G3, MODEL 9390E, POWERHEART AED G3 AUTOMATIC, MODEL 9390A

CLEARED

Sep 10, 2009
72 days to decision

K091943 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k091943/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Jun 30, 2009
Decision date	Sep 10, 2009
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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