FDA 510(k) Premarket Notification

K060934 MODIFICATION TO POWERHEART ECD

CLEARED

May 15, 2006
40 days to decision

K060934 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k060934/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Apr 5, 2006
Decision date	May 15, 2006
Days to decision	40 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k060934/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 4, 2026