

**K012197 POWERHEART CARDIAC RHYTHM MODULE**Nov 16, 2001  
126 days to decisionK012197 · Product code: **MKJ** · CardiovascularSource: <https://www.510kdatabase.net/k012197/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Jul 13, 2001
Decision date	Nov 16, 2001
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardiac Science, Inc.</b>
Location	Minnetonka, MN, US
Contact	Sew-Wah Tay
510(k) history	10 submissions · 8 cleared · 1997-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012197/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 1, 2026