

**K131494 HEART SYNC**Sep 16, 2013  
116 days to decisionK131494 · Product code: **MKJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k131494/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	May 23, 2013
Decision date	Sep 16, 2013
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Heart Sync, Inc.</b>
Location	Naples, FL, US
Contact	DANIEL KAMM
510(k) history	3 submissions · 3 cleared · 2012-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131494/> 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 June 7, 2026