

K120536 HEART SYNC PEDIATRIC PHYSIO AED PADAug 6, 2012
166 days to decisionK120536 · Product code: **MKJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k120536/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Feb 22, 2012
Decision date	Aug 6, 2012
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120536/> 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 7, 2026