

**K081442 HEART SYNC PEDIATRIC, MODEL PED-100**Sep 24, 2008  
125 days to decisionK081442 · Product code: **LDD** · CardiovascularSource: <https://www.510kdatabase.net/k081442/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	May 22, 2008
Decision date	Sep 24, 2008
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Heart Sync, LLC</b>
Location	Ann Arbor, MI, US
Contact	STEPHEN SHULMAN
510(k) history	2 submissions · 2 cleared · 2008-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081442/> 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 24, 2026