

**K123881 HEARTSINE SAMARITAN PAD 350P**Jul 11, 2013  
206 days to decisionK123881 · Product code: **MKJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k123881/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Dec 17, 2012
Decision date	Jul 11, 2013
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Heartsine Technologies, Inc.</b>
Location	Mission Viejo, CA, US
Contact	JAMES MCGUINNESS
510(k) history	6 submissions · 6 cleared · 2003-2015

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123881/> 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 4, 2026