

**K040896 MODIFICATION TO ENCOMPASS**Jul 16, 2004  
101 days to decisionK040896 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k040896/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 6, 2004
Decision date	Jul 16, 2004
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Heartlab, Inc.</b>
Location	Providence, RI, US
Contact	RICHARD PETROCELLI
510(k) history	6 submissions · 6 cleared · 1995-2005

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040896/> 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 May 18, 2026