

**K954860 ECHONET**Dec 21, 1995  
59 days to decisionK954860 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k954860/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received         | Oct 23, 1995                                 |
| Decision date         | Dec 21, 1995                                 |
| Days to decision      | 59 days                                      |
| Third-party review    | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954860/> 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