

**K082366 LIFE BED PATIENT VIGILANCE SYSTEM**Sep 26, 2008  
39 days to decisionK082366 · Product code: **DRT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k082366/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Aug 18, 2008
Decision date	Sep 26, 2008
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hoana Medical, Inc.</b>
Location	Honolulu, HI, US
Contact	NANCY GERTLAR
510(k) history	5 submissions · 5 cleared · 2006-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082366/> 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 21, 2026