

**K082421 HEARTSUITE HEMODYNAMICS 7.10**Dec 17, 2008  
117 days to decisionK082421 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k082421/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Aug 22, 2008
Decision date	Dec 17, 2008
Days to decision	117 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Emageon, Inc.</b>
Location	Madison, WI, US
510(k) history	2 submissions · 2 cleared · 2005-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082421/>, 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