

**K103678 CASE CARDIAC TESTING SYSTEM, CS CARDIAC TESTING SYSTEM**Feb 16, 2011  
62 days to decisionK103678 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k103678/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Dec 16, 2010
Decision date	Feb 16, 2011
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Medical Systems Information Technologies GmbH</b>
Location	Freiburg, DE
Contact	ALBRECHT MALKMUS
510(k) history	3 submissions · 3 cleared · 2000-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103678/>; 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 26, 2026