

**K091594 HEART-EXERCISE**Jul 29, 2009  
57 days to decisionK091594 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k091594/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jun 2, 2009
Decision date	Jul 29, 2009
Days to decision	57 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	PATRICIA TAIGE
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/k091594/> 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