

**K042782 SEER MC**Sep 2, 2005  
331 days to decisionK042782 · Product code: **MLO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k042782/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)
Date received	Oct 6, 2004
Decision date	Sep 2, 2005
Days to decision	331 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ge Medical Systems Information Technologies</b>
Location	Mchenry, IL, US
Contact	GRACE LEMIEUX
510(k) history	136 submissions · 132 cleared · 1978-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042782/> 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