

**K993788 R.TEST EVOLUTION**Aug 4, 2000  
269 days to decisionK993788 · Product code: **MLO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k993788/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)
Date received	Nov 9, 1999
Decision date	Aug 4, 2000
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Novacor Div.</b>
Location	Flemington, NJ, US
Contact	LYNETTE L HOWARD
510(k) history	1 submissions · 1 cleared · 2000-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k993788/> 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 July 3, 2026