

**K042108 VISTA PLUS**Jan 19, 2005  
168 days to decisionK042108 · Product code: **MLO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k042108/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)
Date received	Aug 4, 2004
Decision date	Jan 19, 2005
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Novacor</b>
Location	Rueil Malmaison Cedex, FR
Contact	DOMINIQUE GRENIER
510(k) history	2 submissions · 2 cleared · 2004-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042108/> 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 2, 2026