

K010396 C. NET 2100Oct 4, 2001
237 days to decisionK010396 · Product code: **MLO** · Cardiovascular
Source: <https://www.510kdatabase.net/k010396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)
Date received	Feb 9, 2001
Decision date	Oct 4, 2001
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardionetics, Ltd.
Location	Waltham, MA, US
Contact	BARRY SALL
510(k) history	1 submissions · 1 cleared · 2001-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010396/> Data sourced from FDA 510(k) public records (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. - Generated July 3, 2026