

K992197 MODIFICATION TO ZYMED HOLTER 2000Jul 28, 1999
28 days to decisionK992197 · Product code: **MLO** · CardiovascularSource: <https://www.510kdatabase.net/k992197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)
Date received	Jun 30, 1999
Decision date	Jul 28, 1999
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zymed Medical Instrumentation
Location	Camarillo, CA, US
Contact	GRETEL LUMLEY
510(k) history	7 submissions · 7 cleared · 1993-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992197/> 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