

K992706 GALIX GBI -3S-LPMar 15, 2001
581 days to decisionK992706 · Product code: **MLO** · CardiovascularSource: <https://www.510kdatabase.net/k992706/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)
Date received	Aug 12, 1999
Decision date	Mar 15, 2001
Days to decision	581 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Galix Biomedical Instrumentation, Inc.
Location	Miami Beach, FL, US
Contact	JORDAN GAVRIELIDES
510(k) history	6 submissions · 6 cleared · 1998-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992706/> 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 June 20, 2026