

**K092853 3 CHANNEL DIGITAL AMBULATORY ECG RECORDER
MODEL GALIX GBI-3SM**Jul 9, 2010
296 days to decisionK092853 · Product code: **MLO** · Cardiovascular
Source: <https://www.510kdatabase.net/k092853/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)
Date received	Sep 16, 2009
Decision date	Jul 9, 2010
Days to decision	296 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092853/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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