

**K030145 GALIX WINTER**Sep 17, 2003  
245 days to decisionK030145 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k030145/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jan 15, 2003
Decision date	Sep 17, 2003
Days to decision	245 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Galix Biomedical Instrumentation, Inc.</b>
Location	Miami Beach, FL, US
Contact	EDUARDO REY
510(k) history	6 submissions · 6 cleared · 1998-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030145/> 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 June 20, 2026