

**K001305 MAC-LAB SYSTEM AND CARDIOLAB EP SYSTEM**Jun 27, 2000  
64 days to decisionK001305 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k001305/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Apr 24, 2000
Decision date	Jun 27, 2000
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>General Electric Medical Systems Information Techn</b>
Location	Sugarland, TX, US
Contact	J. LAN MCDONALD
510(k) history	33 submissions · 33 cleared · 1999-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001305/> 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 July 3, 2026