

**K021366 MAC-LAB/CARDIOLAB EP/COMBOLAB**Jul 3, 2002  
64 days to decisionK021366 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k021366/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Apr 30, 2002
Decision date	Jul 3, 2002
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k021366/> 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 May 19, 2026