

K130626 MAC-LAB HEMODYNAMIC RECORDING SYSTEMMay 1, 2013
54 days to decisionK130626 · Product code: **DQK** · CardiovascularSource: <https://www.510kdatabase.net/k130626/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Mar 8, 2013
Decision date	May 1, 2013
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary
Other names	CARDIOLAB ELECTROPHYSIOLOGY RECORDING SYSTEM; COMBOLAB HEMODYNAMIC AND ELECTROPHYS

APPLICANT

Company	Ge Medical Systems Information Technologies, Inc.
Location	Milwaukee, WI, US
Contact	PHILIP MALCA
510(k) history	31 submissions · 31 cleared · 2010-2026

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