

K033492 MODIFICATION TO MAC 5000 ECG ANALYSIS SYSTEMNov 24, 2003
20 days to decisionK033492 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k033492/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Nov 4, 2003
Decision date	Nov 24, 2003
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ge Medical Systems Information Technologies
Location	Mchenry, IL, US
Contact	LISA LEE MICHELS
510(k) history	136 submissions · 132 cleared · 1978-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033492/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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