

K090212 MAC 800 RESTING ECG ANALYSIS SYSTEMFeb 19, 2009
22 days to decisionK090212 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k090212/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrocardiograph (DPS)
Date received	Jan 28, 2009
Decision date	Feb 19, 2009
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ge Medical Syst. Information Technologies
Location	Milwaukee, WI, US
Contact	LARRY LEPLEY
510(k) history	2 submissions · 2 cleared · 2004-2009

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