FDA 510(k) Premarket Notification

K081437 MAC 1600 ECG ANALYSIS SYSTEM

CLEARED

Jul 15, 2008
54 days to decision

K081437 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k081437/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	May 22, 2008
Decision date	Jul 15, 2008
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k081437/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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