FDA 510(k) Premarket Notification

CLEARED

K073462 MODIFICATION TO DASH 3000, 4000, 5000 MONITOR AND ACCESSORIES

Jan 11, 2008
32 days to decision

K073462 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k073462/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Dec 10, 2007
Decision date	Jan 11, 2008
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k073462/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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