FDA 510(k) Premarket Notification

K090702 MODIFICATION TO DASH 2500 PATIENT MONITOR

CLEARED

Apr 15, 2009
29 days to decision

K090702 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k090702/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Mar 17, 2009
Decision date	Apr 15, 2009
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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