FDA 510(k) Premarket Notification

K062233 HEARTSTART MRX MONITOR/DEFIBRILLATOR

CLEARED

Nov 22, 2006
112 days to decision

K062233 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k062233/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Aug 2, 2006
Decision date	Nov 22, 2006
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medical Systems North America, Inc.**
Location	Shelton, CT, US
Contact	MICHAEL J DOYLE
510(k) history	71 submissions · 71 cleared · 1989-2010