FDA 510(k) Premarket Notification

K092391 MOBILEAED, MOBILEALS, MOBILEAED+ AND ADVANTAGEAED

CLEARED

Apr 1, 2010
239 days to decision

K092391 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k092391/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Aug 5, 2009
Decision date	Apr 1, 2010
Days to decision	239 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Concord Medical Products**
Location	Burlington, MA, US
Contact	RANDALL FINCKE
510(k) history	1 submissions · 1 cleared · 2010-2010