FDA 510(k) Premarket Notification

K112190 PATIENT MONITOR

CLEARED

Nov 9, 2011
103 days to decision

K112190 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k112190/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 29, 2011
Decision date	Nov 9, 2011
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mediana Co., Ltd.**
Location	Flintville, TN, US
Contact	CHARLIE MACK
510(k) history	10 submissions · 10 cleared · 2005-2020