FDA 510(k) Premarket Notification

CLEARED

K132075 PASSPORT M SERIES PATIENT MONITORING (INCLUDING MODELS PASSPORT 17M AND PASSPORT 12M)

Apr 18, 2014
289 days to decision

K132075 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k132075/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 3, 2013
Decision date	Apr 18, 2014
Days to decision	289 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mindray North America**
Location	Mahwh, NJ, US
Contact	RUSSELL OLSEN
510(k) history	3 submissions · 3 cleared · 2014-2014