

**K132075 PASSPORT M SERIES PATIENT MONITORING  
(INCLUDING MODELS PASSPORT 17M AND PASSPORT 12M)**Apr 18, 2014  
289 days to decisionK132075 · 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	<b>Mindray North America</b>
Location	Mahwh, NJ, US
Contact	RUSSELL OLSEN
510(k) history	3 submissions · 3 cleared · 2014-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132075/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 7, 2026