

K143195 Passport Series Patient Monitors (including Passport 17M, Passport 12M and T1)Dec 22, 2014
46 days to decisionK143195 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k143195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Nov 6, 2014
Decision date	Dec 22, 2014
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Location	Great Neck, NY, US
Contact	Yanhong Bai
510(k) history	9 submissions · 9 cleared · 2012-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143195/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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