

K153448 Passport Series Patient Monitors (Including Passport 8, Passport 12)

Mar 3, 2016
94 days to decisionK153448 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k153448/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Nov 30, 2015
Decision date	Mar 3, 2016
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Location	Shenzhen, CN
Contact	BAI YANHONG
Website	https://www.mindray.com
510(k) history	156 submissions · 156 cleared · 2004-2026

Shenzhen Mindray Bio-Medical Electronics Co., Ltd. is a medical technology and solutions supplier headquartered in Shenzhen, China. The company develops diagnostic imaging, patient monitoring, and clinical care devices. Mindray has received FDA 510(k) clearances from total submissions since 2004. The company specializes in diagnostic ultrasound systems and radiology devices, with a strong portfolio spanning general imaging, women's healthcare, cardiology, and liver care applications. Recent clearances include multiple ultrasound system variants and central monitoring plat...

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Device record: <https://www.510kdatabase.net/k153448/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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