

**K190011 Passport Series Patient Monitors (including Passport 17m, Passport 12m and T1)**Jul 10, 2019  
188 days to decisionK190011 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k190011/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jan 3, 2019
Decision date	Jul 10, 2019
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Yanhong Bai
Website	<a href="https://www.mindray.com">https://www.mindray.com</a>
510(k) history	158 submissions · 158 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...