

**K260098 ePM Series Patient Monitor (ePM 10/ePM 10A/ePM 10C/Guardian plus/ ePM 12/ePM 12A/ePM 12C / ePM 15/ePM 15A/ePM 15C /ePM 10M/ ePM 10MA/ ePM 10MC/ePM 12M/ ePM 12MA/ ePM 12MC/ePM 15M/ ePM 15MA/ ePM 15MC)**

May 20, 2026  
127 days to decision

K260098 · Product code: **MHX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k260098/>

**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 13, 2026
Decision date	May 20, 2026
Days to decision	127 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	Li Lei
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...