FDA 510(k) Premarket Notification

CLEARED

K062194 HYPERVISOR VI CENTRAL MONITORING SYSTEM

Apr 11, 2007
254 days to decision

K062194 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k062194/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 31, 2006
Decision date	Apr 11, 2007
Days to decision	254 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
Location	Shenzhen, CN
Contact	SUSAN D GOLDSTEIN-FALK
Website	https://www.mindray.com
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...

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Device record: https://www.510kdatabase.net/k062194/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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