FDA 510(k) Premarket Notification

CLEARED

K150352 V Series Monitoring System (including V12 and V21 Monitors)

Sep 2, 2015
203 days to decision

K150352 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k150352/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Feb 11, 2015
Decision date	Sep 2, 2015
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
Location	Shenzhen, CN
Contact	YANHONG BAI
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...