

K193391 BeneVision Central Monitoring SystemMay 21, 2020
167 days to decisionK193391 · Product code: **MSX** · Cardiovascular
Source: <https://www.510kdatabase.net/k193391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Network And Communication, Physiological Monitors (MSX)
Date received	Dec 6, 2019
Decision date	May 21, 2020
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	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	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/k193391/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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