

**K230768 M9/M9CV/M9T/M8 Elite/M10/M10CV/Crius  
M10/M11/M11CV/Crius M11/Operus M11/M9 Premium  
Diagnostic Ultrasound System**Jun 9, 2023  
81 days to decisionK230768 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k230768/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 20, 2023
Decision date	Jun 9, 2023
Days to decision	81 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	Tang Jing
Website	<a href="https://www.mindray.com">https://www.mindray.com</a>
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...

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