

**K162267 Resona 7/Resona 7CV/Resona 7EXP/Resona 7S/Resona 7OB Diagnostic Ultrasound System**Sep 6, 2016  
26 days to decisionK162267 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k162267/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 11, 2016
Decision date	Sep 6, 2016
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Zhai Pei
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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