

**K250024 TE Air Diagnostic Ultrasound System**May 30, 2025  
144 days to decisionK250024 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k250024/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 6, 2025
Decision date	May 30, 2025
Days to decision	144 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	Jufang Shi
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&apos;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/k250024/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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