

**K220242 TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite, TEX10/ TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite Diagnostic Ultrasound System**Mar 25, 2022  
56 days to decisionK220242 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k220242/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 28, 2022
Decision date	Mar 25, 2022
Days to decision	56 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	Jiang Xiaoyong
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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