

**K212265 TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20
Elite Diagnostic Ultrasound System, TEX10/ TEX10
Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite
Diagnostic Ultrasound System**

Nov 16, 2021
119 days to decision

K212265 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k212265/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 20, 2021
Decision date	Nov 16, 2021
Days to decision	119 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	Hao Yixuan
Website	https://www.mindray.com
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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Device record: <https://www.510kdatabase.net/k212265/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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