

K241201 TEX20/TEX20 Pro/TEX20S/TEX20T/TEX20 Exp/TEX20 Elite/TEX10/TEX10 Pro/TEX10S/TEX10T/TEX10 Exp/TEX10 Elite/TE X/TE X Lite/Anesus TEX20 Pro/Eagus TEX20/Eagus TEX20T/Eagus TEX21/Eagus TEX21T/Eros/TE X Plus/Anesus TEX10 Pro/TEX9U/TEX9M/Eagus TEX11/Eagus TEX11T/Eagus/TEX10/Eagus TEX10T/Eagus TEX/Ares Diagnostic Ultrasound System

Sep 16, 2024
139 days to decision

K241201 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k241201/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 30, 2024
Decision date	Sep 16, 2024
Days to decision	139 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	Zhang Yuxi
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...