FDA 510(k) Premarket Notification

CLEARED

K251192 Diagnostic Ultrasound System (MX7)

Aug 22, 2025
127 days to decision

K251192 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k251192/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 17, 2025
Decision date	Aug 22, 2025
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Diagnostic Ultrasound System (MX7T); Diagnostic Ultrasound System (Vaus7); Diagnostic Ultrasound System (Zeus); Diagnostic Ultrasound System (ME7); Diagnostic Ultrasound System (Anesus ME7); Diagnostic Ultrasound System (Anesus ME7T); Diagnostic Ultrasound System (MX7P); Diagnostic Ultrasound System (MX7W); Diagnostic Ultrasound System (MX8); Diagnostic Ultrasound System (MX8T); Diagnostic Ultrasound System (Vaus8); Diagnostic Ultrasound System (ME8)

APPLICANT

Company	**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
Location	Shenzhen, CN
Contact	Jing Tang
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...