

K250110 Diagnostic Ultrasound System (MX6)May 16, 2025
120 days to decisionK250110 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k250110/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 16, 2025
Decision date	May 16, 2025
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Diagnostic Ultrasound System (MX6S); Diagnostic Ultrasound System (MX6T); Diagnostic Ultrasound System (MX6 Exp); Diagnostic Ultrasound System (MX6 Pro); Diagnostic Ultrasound System (MX6 Super); Diagnostic Ultrasound System (MXG); Diagnostic Ultrasound System (Emerus MX6); Diagnostic Ultrasound System (Emerus MX6 Exp); Diagnostic Ultrasound System (Anesus MX6); Diagnostic Ultrasound System (Anesus MX6 Exp); Diagnostic Ultrasound System (Crius MX6);

APPLICANT

Company	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Location	Shenzhen, CN
Contact	Wei Zhang
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...