

K260846 Diagnostic Ultrasound System (MU9)

May 11, 2026
56 days to decision

K260846 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k260846/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 16, 2026
Decision date	May 11, 2026
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Diagnostic Ultrasound System (MU9S);Diagnostic Ultrasound System (MU9T);Diagnostic Ultrasound System (MU9 Exp);Diagnostic Ultrasound System (MU9 Pro);Diagnostic Ultrasound System (MU9 Super);Diagnostic Ultrasound System (MU9P);Diagnostic Ultrasound System (MU9A);Diagnostic Ultrasound System (MU7);Diagnostic Ultrasound System (MU7S);Diagnostic Ultrasound System (MU7T);Diagnostic Ultrasound System (MU7 Exp);Diagnostic Ultrasound System (MU7 Pro);Diagnos

APPLICANT

Company	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Location	Shenzhen, CN
Contact	Xiaolong Fan
Website	https://www.mindray.com
510(k) history	158 submissions · 158 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...