FDA 510(k) Premarket Notification

CLEARED

K250020 Diagnostic Ultrasound System (Recho R9W)

May 19, 2025
136 days to decision

K250020 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k250020/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 3, 2025
Decision date	May 19, 2025
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Diagnostic Ultrasound System (Recho R9); Diagnostic Ultrasound System (Recho R9 Pro); Diagnostic Ultrasound System (Recho R9 Exp); Diagnostic Ultrasound System (Recho R9S); Diagnostic Ultrasound System (Recho R9T); Diagnostic Ultrasound System (Crius R9 CV); Diagnostic Ultrasound System (Anesus R9 CV); Diagnostic Ultrasound System (Recho R9 Super); Diagnostic Ultrasound System (Recho R9 Lumi); Diagnostic Ultrasound System (Recho R CV); Diagnost

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...