

K240115 Resona I8W, Resona I8, Resona I8 Exp, Resona I8S, Resona I8T, Resona IY, Resona I8 Easi, Eagus I8 Easi, Nuewa I8W, Nuewa I8, Nuewa I8 Exp, NuewaI8S, Nuewa I8T, Imagyn I8, Imagyn I8S, Imagyn I8T, Imagyn I8 Exp, Nuewa IY Diagnostic Ultrasound System

Apr 22, 2024
97 days to decision

K240115 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k240115/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 16, 2024
Decision date	Apr 22, 2024
Days to decision	97 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	Tang Jing
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...