FDA 510(k) Premarket Notification

CLEARED

Jun 17, 2024
97 days to decision

K240684 Resona I9, Resona I9 Exp, Resona I9S, Resona I9T, Resona I9 Easi, Resona I9 Nasa, Resona IV, Imagyn I9, Imagyn I9S, Imagyn I9 Easi, Nuewa I9, Nuewa I9S, Nuewa I9T, Nuewa I9 Exp, Nuewa I9 Easi, Anesus I9, Anesus I9 Easi, Eagus I9, Resona I9W, Recho I9, Recho I9 Pro, Recho I9 Exp, Recho I9S, Recho I9T Diagnostic Ultrasound System

K240684 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k240684/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Mar 12, 2024
Decision date	Jun 17, 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...