FDA 510(k) Premarket Notification

CLEARED

Feb 7, 2023
134 days to decision

K222928 Resona R9/ Resona R9 Exp/ Resona R9 Pro/ Resona R9S/ Nuewa R9/ Nuewa R9 Exp Diagnostic Ultrasound Sysem, Nuewa R9 Pro/ Nuewa R9S/ Resona 7/ Resona 7CV/Resona 7EXP/Resona 7S/ Resona 70B Diagnostic Ultrasound System, Resona 7PRO/Imagyn 7/ Resona Y/Resona R9W/Resona R7W Nuewa R9W/Nuewa R7W Diagnostic Ultrasound System

K222928 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k222928/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 26, 2022
Decision date	Feb 7, 2023
Days to decision	134 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	Zhang Wei
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...