

K242231 Resona A10S, Resona A20 Pro, Resona A20T, Resona A20S, Resona A20W, Resona A20, Resona A20 Exp, Resona A20 Premium, Resona A20 Elite, Resona A20 Plus, Resona A Elite, Resona A MV, Eagus A20W, Eagus A20 Diagnostic Ultrasound SystemNov 8, 2024
101 days to decisionK242231 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k242231/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jul 30, 2024
Decision date	Nov 8, 2024
Days to decision	101 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	Jiahong Jin
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...