

K253049 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 System

Feb 11, 2026
142 days to decision

K253049 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k253049/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Sep 22, 2025
Decision date	Feb 11, 2026
Days to decision	142 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...