

K251853 Consona N5, Consona N5 Pro, Consona N5 Super, Consona N5 Exp, Consona ER, Consona N5S, Consona EI, Consona EF, Consona N5 Elite, Consona N5 Ultra, Consona N3, Consona N3 Exp Diagnostic Ultrasound System

Nov 7, 2025
143 days to decision

K251853 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k251853/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jun 17, 2025
Decision date	Nov 7, 2025
Days to decision	143 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	Lu Chen
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...