

K221300 Consona N9, Consona N9 Pro, Consona N9 Super, Consona Nova, Consona N9S, Consona NI, Consona NT, Nuewa N9, Recho N9, Consona N9 Exp, Consona N9 Elite, Resona N9, Consona N9T, Consona N8, Consona N8 Pro, Consona N8 Super, Consona OR, Consona N8S, Consona OI, Consona OT, Consona N8 Exp, Consona N8 Elite, Consona N8T, Consona N7, Consona N7 Pro, Consona N7 Super, Consona VR, Consona N7S, Consona VI, Consona VT, Consona N7 Exp, Consona N7 Elite, Consona N7T Diagnostic Ultrasound System

Sep 29, 2022
147 days to decision

K221300 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k221300/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 5, 2022
Decision date	Sep 29, 2022
Days to decision	147 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...