

K221496 Consona N6, Consona N6 Pro, Consona N6 Super, Consona AR, Consona N6S, Consona AE, Consona AT, Consona N6 Exp Diagnostic Ultrasound System, Consona N6 Elite, Consona N6T Diagnostic Ultrasound SystemSep 29, 2022
129 days to decisionK221496 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k221496/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 23, 2022
Decision date	Sep 29, 2022
Days to decision	129 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...