

K200001 MX7/ MX7T/ Vaus7/ Zeus Diagnostic Ultrasound System, ME7/ Anesus ME7/ Anesus ME7T Diagnostic Ultrasound System, MX8/ MX8T/ Vaus8/ ME8 Diagnostic Ultrasound SystemApr 9, 2020
98 days to decisionK200001 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k200001/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Jan 2, 2020
Decision date	Apr 9, 2020
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Location	Shenzhen, CN
Contact	Shi Jufang
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...

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