

**K192152 DC-80/DC-80 PRO/DC-80  
EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ  
Diagnostic Ultrasound System**

Dec 13, 2019  
126 days to decision

K192152 · Product code: IYN · Radiology  
Source: <https://www.510kdatabase.net/k192152/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Aug 9, 2019
Decision date	Dec 13, 2019
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Mindray Bio-Medical Electronics Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Zhang Wei
Website	<a href="https://www.mindray.com">https://www.mindray.com</a>
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...