

**K053346 MODIFICATION TO: DP-9900 DIGITAL ULTRASONIC
DIAGNOSTIC IMAGING SYSTEM, MODEL DP-9900**Dec 9, 2005
7 days to decisionK053346 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k053346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Dec 2, 2005
Decision date	Dec 9, 2005
Days to decision	7 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Location	Shenzhen, CN
Contact	SUSAN D GOLSTEIN-FALK
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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Device record: <https://www.510kdatabase.net/k053346/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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