CLEARED

K123185 DC-8/DC-8 PRO/DC-8, CV/DC-8, EXP/DC-8S DIAGNOSTIC ULTRASOUND SYSTEM

Nov 2, 2012
23 days to decision

K123185 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k123185/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Oct 10, 2012
Decision date	Nov 2, 2012
Days to decision	23 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
Location	Shenzhen, CN
Contact	ZHAI PEI
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...