

**K183377 DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic
Ultrasound System**Apr 4, 2019
119 days to decisionK183377 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k183377/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Dec 6, 2018 |
| Decision date | Apr 4, 2019 |
| Days to decision | 119 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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Device record: <https://www.510kdatabase.net/k183377/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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