

K172860 Resona 6/Resona 6T/Resona 6EXP/Resona 6Elite Diagnostic Ultrasound System/Resona 6S/Resona 6PRO/Resona 6OB Diagnostic Ultrasound System /Resona 5/Resona 5T/Resona 5EXP/Resona 5Elite Diagnostic Ultrasound System

Jan 2, 2018
104 days to decision

K172860 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k172860/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Sep 20, 2017 |
| Decision date | Jan 2, 2018 |
| Days to decision | 104 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shenzhen Mindray Bio-Medical Electronics Co., Ltd. |
| Location | Shenzhen, CN |
| Contact | Ma Chao |
| 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...