

K171311 A5 Anesthesia SystemJan 12, 2018
255 days to decisionK171311 · Product code: **BSZ** · Anesthesiology
Source: <https://www.510kdatabase.net/k171311/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gas-machine, Anesthesia (BSZ) |
| Date received | May 2, 2017 |
| Decision date | Jan 12, 2018 |
| Days to decision | 255 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shenzhen Mindray Bio-Medical Electronics Co., Ltd. |
| Location | Shenzhen, CN |
| Contact | Yanhong Bai |
| 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...
