

K253330 A5 Anesthesia System (A5)Jun 25, 2026
268 days to decisionK253330 · Product code: **BSZ** · Anesthesiology
Source: <https://www.510kdatabase.net/k253330/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gas-machine, Anesthesia (BSZ)
Date received	Sep 30, 2025
Decision date	Jun 25, 2026
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	A7 Anesthesia System (A7)

APPLICANT

Company	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Location	Shenzhen, CN
Contact	Li Lei
Website	https://www.mindray.com
510(k) history	159 submissions · 159 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...