

K112377 BS-400 CHEMISTRY ANALYZER, CLC 720 CHEMISTRY ANALYZERMar 23, 2012
219 days to decisionK112377 · Product code: **CFR** · Chemistry
Source: <https://www.510kdatabase.net/k112377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Aug 17, 2011
Decision date	Mar 23, 2012
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Location	Shenzhen, CN
Contact	SUSAN D GOLDSTEIN-FALK
Website	https://www.mindray.com
510(k) history	158 submissions · 158 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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