

**K093394 BC-3200 AUTO HEMATOLOGY ANALYZER,M-30D
DILUENT, M-30R RINSE, M-30CFL LYSE, M-30E-Z CLEANSER,
M-30PROBE CLEANSER, BC-3D C**Apr 8, 2010
160 days to decisionK093394 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k093394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Oct 30, 2009
Decision date	Apr 8, 2010
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Location	Shenzhen, CN
Contact	SUSAN GOLDSTEIN
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...