

K160429 BC-5390 Auto Hematology AnalyzerSep 1, 2016
198 days to decisionK160429 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k160429/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Feb 16, 2016
Decision date	Sep 1, 2016
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mindray Bio-Medical Electronics Co., Ltd.
Location	Shenzhen, CN
Contact	Min Zheng
Website	http://www.mindray.com/
510(k) history	2 submissions · 2 cleared · 2015-2016

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