

**K081213 BD FACSCOUNT CD4 REAGENTS WITH MODEL
339010**Aug 14, 2008
106 days to decisionK081213 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k081213/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Apr 30, 2008
Decision date	Aug 14, 2008
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bd Biosciences
Location	San Jose, CA, US
Contact	NOBUKO NAKAJIMA
510(k) history	10 submissions · 10 cleared · 2000-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081213/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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