

K041074 BD FACSCANTO WITH BD FACSCANTO SOFTWARESep 17, 2004
144 days to decisionK041074 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k041074/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Apr 26, 2004
Decision date	Sep 17, 2004
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041074/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 5, 2026