

**K971205 TRI TEST REAGENT CD4 FIT C/CD8 PE/CD3 PERCP
WITH TRUCOUNT ABSOLUTE COUNT TUBES**Dec 1, 1997
244 days to decisionK971205 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k971205/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Apr 1, 1997
Decision date	Dec 1, 1997
Days to decision	244 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Becton Dickinson Immunocytometry Systems
Location	San Jose, CA, US
Contact	ANNA LONGWELL
510(k) history	21 submissions · 21 cleared · 1989-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971205/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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