

**K964856 CD3 FITC/CD19 R-PE/CD45 TRI-COLOR
MONOCLONAL ANTIBODY COMBINATION**Jan 17, 1997
44 days to decisionK964856 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k964856/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Dec 4, 1996
Decision date	Jan 17, 1997
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Caltag Laboratories, Inc.
Location	South San Francisco, CA, US
Contact	DAVID C BISHOP, PH.D.
510(k) history	12 submissions · 12 cleared · 1995-1999

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