

**K950917 CD3 FITC/CD8 R-PE/CD45 TRI-COLOR MONOCLONAL
ANTIBODY COMBINATION**Dec 21, 1995
295 days to decisionK950917 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k950917/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Mar 1, 1995
Decision date	Dec 21, 1995
Days to decision	295 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Caltag Laboratories, Inc.
Location	South San Francisco, CA, US
Contact	TONY LAM
510(k) history	12 submissions · 12 cleared · 1995-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k950917/>; 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 28, 2026