

**K951073 CD3 TRI-COLOR/CD4 R-PE/CD8 FITC MONOCLONAL
ANTIBODY COMBINATION**Dec 21, 1995
288 days to decisionK951073 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k951073/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Mar 8, 1995
Decision date	Dec 21, 1995
Days to decision	288 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/k951073/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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