

**K950918 CD3 FITC/CD4 R-PE MONOCLONAL ANTIBODY  
COMBINATION**Dec 21, 1995  
295 days to decisionK950918 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k950918/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950918/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026