

**K963954 CD 19 R-PE, CD19 TRI-COLOR MONOCLONAL ANTIBODY**Nov 25, 1996  
54 days to decisionK963954 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k963954/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Oct 2, 1996
Decision date	Nov 25, 1996
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Caltag Laboratories, Inc.</b>
Location	South San Francisco, CA, US
Contact	DAVID C BISHOP
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/k963954/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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