

**K982166 CYTO-STAT TRICHROME  
CD45-FITC/CD56-RD1/CD3-PC5 MONOCLONAL ANTIBODY  
REAGENT WITH CYTO-STAT TRICHROME  
CD45-FITC/MSIGG1-RD1**Nov 5, 1998  
139 days to decisionK982166 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k982166/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jun 19, 1998
Decision date	Nov 5, 1998
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coulter Corp.</b>
Location	Hialeah, FL, US
Contact	MARION S GAIDE
510(k) history	51 submissions · 51 cleared · 1989-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k982166/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026