

**K964618 CYTO-STAT TRICHROME CD8-FITC/CD4-RDI/CD3-PC5  
MONOCLONAL ANTIBODY REAGENT WITH CYTO-STAT  
TRICHROME MSIGGI-FITC/MSIGGI-RD1**

Dec 23, 1996  
69 days to decision

K964618 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k964618/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Oct 15, 1996
Decision date	Dec 23, 1996
Days to decision	69 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/k964618/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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