

**K962305 CYTO-STAT TRICHROME
CD45-FITC/CD8-RD1/CD3-PC5 MONOCLONAL ANTIBODY
REAGENT IWTH ISOTYPIC CONTROL**Jan 6, 1997
203 days to decisionK962305 · Product code: **GKZ** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jun 17, 1996
Decision date	Jan 6, 1997
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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