

**K990172 TETRAONE SYSTEM FOR EPICS XL FLOW
CYTOMETRY SYSTEMS WITH CYTO-STAT TETRACHROME
CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 MONOCLA**Apr 13, 1999
84 days to decisionK990172 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k990172/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jan 19, 1999
Decision date	Apr 13, 1999
Days to decision	84 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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