

**K963263 TETRAONE SYSTEM FOR EPICS XL FLOW  
CYTOMETRY SYSTEMS AND CYTO-STAT TERTRACHROME  
CD45-FITC/CD4-RDI/CD8-ECD/CD3-PC5**Jan 22, 1997  
155 days to decisionK963263 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k963263/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Aug 20, 1996
Decision date	Jan 22, 1997
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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