

**K950742 CYTO-STAT/COULTER CLONE
CD3-ECD/T4-RD1/T8-FITC MONOCLONAL ANTIBOEY REAGENT**Aug 25, 1995
189 days to decisionK950742 · Product code: **GKZ** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Feb 17, 1995
Decision date	Aug 25, 1995
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coulter Corp.
Location	Hialeah, FL, US
Contact	BENITA B BOURQUE
510(k) history	51 submissions · 51 cleared · 1989-2000

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