

**K926124 CYTO-STAT/COULTER CLONE CD3
(IGG1)-FITC/B4-RD1 MON**Jul 6, 1993
214 days to decisionK926124 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k926124/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Dec 4, 1992
Decision date	Jul 6, 1993
Days to decision	214 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Coulter Corp.
Location	Hialeah, FL, US
Contact	GREGORY M BUTCHKO
510(k) history	51 submissions · 51 cleared · 1989-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k926124/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026