

**K922745 CYTO-STAT/COULTER CLONE
CD3(IGG1)-FITC/T4-RD1**Feb 5, 1993
242 days to decisionK922745 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k922745/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jun 8, 1992
Decision date	Feb 5, 1993
Days to decision	242 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Coulter Immunology
Location	Hialeah, FL, US
Contact	GAIDE
510(k) history	16 submissions · 16 cleared · 1988-1993

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k922745/> 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 29, 2026