

**K910473 CYTO-STAT(R)/COULTER CLONE(R) T11-RD1/B4-FITC**Oct 31, 1991  
269 days to decisionK910473 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k910473/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Feb 4, 1991
Decision date	Oct 31, 1991
Days to decision	269 days
Third-party review	No

**APPLICANT**

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Company	<b>Coulter Immunology</b>
Location	Hialeah, FL, US
Contact	GREGORY M BUTCHKO
510(k) history	16 submissions · 16 cleared · 1988-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k910473/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026