

K883753 COULTER CLONE T1 MONOCLONAL ANTIBODYFeb 3, 1989
154 days to decisionK883753 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k883753/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Sep 2, 1988
Decision date	Feb 3, 1989
Days to decision	154 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k883753/>; 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