

K894179 COULTER CLONE(R) MY4 MONOCLONAL ANTIBODYFeb 12, 1990
241 days to decisionK894179 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k894179/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jun 16, 1989
Decision date	Feb 12, 1990
Days to decision	241 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/k894179/>; 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