

K914846 CD2 MONOCLONAL ANTIBODIESJun 19, 1992
235 days to decisionK914846 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k914846/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Oct 28, 1991
Decision date	Jun 19, 1992
Days to decision	235 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Gen Trak, Inc.
Location	Plymouth Meeting, PA, US
Contact	DEBORAH L.LINDEMUTH
510(k) history	5 submissions · 5 cleared · 1992-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k914846/> 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