

**K922085 MONOCLONAL ANTIBODY IGG2A ISOTYPE CONT.
FLOW CYTOM**

Jul 28, 1992
85 days to decision

K922085 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k922085/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	May 4, 1992
Decision date	Jul 28, 1992
Days to decision	85 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.net

Device record: <https://www.510kdatabase.net/k922085/> 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