

**K922084 MONOMCLONAL ANTIBODY IGG1 ISOTYPE CONT.
FLOW CYTOM**Jul 28, 1992
85 days to decisionK922084 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k922084/>**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.netDevice record: <https://www.510kdatabase.net/k922084/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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