

K953498 OPTICLONE IGG1 FITC/IGG1 PE ISOTYPIC CONTROLSep 8, 1995
44 days to decisionK953498 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k953498/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jul 26, 1995
Decision date	Sep 8, 1995
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Immunotech, Inc.
Location	Westbrook, ME, US
Contact	JAMES W CHAMPLIN
510(k) history	3 submissions · 3 cleared · 1995-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953498/> 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 28, 2026