

K954188 OPTICLONE IGG1 FITC/IGG2A PE ISOTYPIC CONTROLNov 3, 1995
58 days to decisionK954188 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k954188/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Sep 6, 1995
Decision date	Nov 3, 1995
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Immunotech Corp.
Location	Mchenry, IL, US
Contact	JAMEES W CHAMPLIN
510(k) history	37 submissions · 37 cleared · 1980-1995

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