

**K964754 ORTHO-MUNE OKB (CD19)- MONOCLONAL
ANTIBODY (MURINE) PHYCOERYTHRINE CONJUGATE**Jan 22, 1997
56 days to decisionK964754 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k964754/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Nov 27, 1996
Decision date	Jan 22, 1997
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho Diagnostic Systems, Inc.
Location	Carpinteria, CA, US
Contact	JOANNE HARRIS
510(k) history	126 submissions · 126 cleared · 1981-1997

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