

**K932532 ORTHO-MUNE OKT8 (CD8) MONOCLONAL ANTIBODY
(MURINE)**Apr 26, 1995
708 days to decisionK932532 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k932532/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	May 18, 1993
Decision date	Apr 26, 1995
Days to decision	708 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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