

**K950625 ORTHO-MUNE OK-COMBO CD40FITC/CD8-PE
(OKT4A/OKT8) MONOCLONAL ANTIBODY (MURINE)**May 13, 1996
458 days to decisionK950625 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k950625/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Feb 10, 1995
Decision date	May 13, 1996
Days to decision	458 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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