

K950482 ORTHO-MUNE OK-COMVO CD3-FITC/CD8-PE (OKT 3/OKT8) MONOCLONAL ANTIBODY (MURINE)May 10, 1996
462 days to decisionK950482 · Product code: **GKZ** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Feb 3, 1995
Decision date	May 10, 1996
Days to decision	462 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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