

K904253 ORTHO MUNE OKT3,4, AND 8 MONOCLONAL ANTIBODYMay 20, 1991
248 days to decisionK904253 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k904253/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Sep 14, 1990
Decision date	May 20, 1991
Days to decision	248 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k904253/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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