

K951459 ORTHO-MUNE OKT 4A (CD4) - MONOCLONAL ANTIBODY (MURINE) FITC CONJUGATE

Jul 14, 1997
837 days to decision

K951459 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k951459/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Mar 30, 1995
Decision date	Jul 14, 1997
Days to decision	837 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k951459/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026