

**K951100 ORTHO-MUNE OK-COMBO CD3-FITC/CD19-PE  
(OKT3/OKB19A MONOCLONAL ANTIBODY (MURINE))**

May 13, 1996  
430 days to decision

K951100 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k951100/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Mar 10, 1995
Decision date	May 13, 1996
Days to decision	430 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k951100/> 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