

**K935720 ORTHO COUNT CALIBRATION KIT FOR ORTHO
CYTORONABSOLUTE LASER FLOW CYTOMETRY SYSTEM**May 9, 1996
891 days to decisionK935720 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k935720/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Nov 30, 1993
Decision date	May 9, 1996
Days to decision	891 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k935720/> 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