

K954570 ORTHO IMMUNOCOUNT FLOW CYTOMETRY SYSTEMApr 30, 1996
211 days to decisionK954570 · Product code: **GKZ** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Oct 2, 1995
Decision date	Apr 30, 1996
Days to decision	211 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

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