

K933878 ZYMMUNE(TM) CD4/CD8 CELL MONITORING KITNov 14, 1995
827 days to decisionK933878 · Product code: **GKZ** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Aug 9, 1993
Decision date	Nov 14, 1995
Days to decision	827 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intracel Corp.
Location	Cambridge, MA, US
Contact	CYNTHIA A SINCLAIR
510(k) history	5 submissions · 5 cleared · 1995-2000

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