

**K980858 MULTITEST CD3/CD16+56/CD45/CD19 REAGENT AND
MULTITEST IMK KIT LYSING SOLUTION**May 22, 1998
78 days to decisionK980858 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k980858/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Mar 5, 1998
Decision date	May 22, 1998
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Becton Dickinson Immunocytometry Systems
Location	San Jose, CA, US
Contact	CINDY MORROW
510(k) history	21 submissions · 21 cleared · 1989-2004

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