

K982172 CYTO-STAT CD3-FITC/CD56-RDI MONOCLONAL ANTIBODY REAGENT WITH CYTO-STAT/COULTER CLONE MSIGGI-RD1/MSIGGI-FITC ISOTYPIC COL

Sep 24, 1998
97 days to decision

K982172 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k982172/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jun 19, 1998
Decision date	Sep 24, 1998
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coulter Corp.
Location	Hialeah, FL, US
Contact	MARION S GIDE
510(k) history	51 submissions · 51 cleared · 1989-2000

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Device record: <https://www.510kdatabase.net/k982172/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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