

K964974 MOUSE ANTI-HUMAN CD45, LEUCOCYTE COMMON ANTIGEN (LCA)/FITC AND CD14, MONOCYTE/RPE

Jun 24, 1997
194 days to decision

K964974 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k964974/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Dec 12, 1996
Decision date	Jun 24, 1997
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dako Corp.
Location	Mchenry, IL, US
Contact	GRETCHEN M MURRAY, PH.D., RAC
510(k) history	54 submissions · 54 cleared · 1981-2002

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Device record: <https://www.510kdatabase.net/k964974/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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