

K961435 MOUSE ANTI-HUMAN CD2, T-CELL/FITC AND MOUSE ANTI-HUMAN CD19, B-CELL/RPE

Jun 14, 1996
60 days to decision

K961435 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k961435/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Counter, Differential Cell (GKZ) |
| Date received | Apr 15, 1996 |
| Decision date | Jun 14, 1996 |
| Days to decision | 60 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 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k961435/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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