

**K980635 DAKO MOUSE ANTI-HUMAN B-CELL, CD19/RPE-CY5,  
CLONE HD37**

Jul 22, 1998  
153 days to decision

K980635 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k980635/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Feb 19, 1998
Decision date	Jul 22, 1998
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dako Corp.</b>
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/k980635/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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