

**K953643 HEMATIL 18 (H-18)**Mar 22, 1996  
231 days to decisionK953643 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k953643/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Aug 4, 1995
Decision date	Mar 22, 1996
Days to decision	231 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Texas Intl. Laboratories, Inc.</b>
Location	Mchenry, IL, US
Contact	YVES LEBIHAN
510(k) history	10 submissions · 10 cleared · 1983-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k953643/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026