

**K945678 DATACELL 18MS**Sep 12, 1995  
298 days to decisionK945678 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k945678/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Nov 18, 1994
Decision date	Sep 12, 1995
Days to decision	298 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Danam Electronics</b>
Location	Walker, MI, US
Contact	JERRY WEST
510(k) history	4 submissions · 4 cleared · 1984-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945678/> 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