

**K911626 SYSTEM 9000, INTERPRETIVE DIFF CELL COUNTER**Sep 13, 1991  
155 days to decisionK911626 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k911626/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Apr 11, 1991
Decision date	Sep 13, 1991
Days to decision	155 days
Third-party review	No

**APPLICANT**

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Company	<b>Serono Baker Diagnostics System</b>
Location	Allentown, PA, US
Contact	DAVID B THOMAS
510(k) history	1 submissions · 1 cleared · 1991-1991

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k911626/>, 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 29, 2026