

**K953598 SERIES 9100 PLUS AUTOMATED DIFFERENTIAL  
HEMATOLOGY ANALYZERS**Mar 11, 1996  
223 days to decisionK953598 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k953598/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Aug 1, 1995
Decision date	Mar 11, 1996
Days to decision	223 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Serono Diagnostics, Inc.</b>
Location	Walker, MI, US
Contact	HOWARD M HOLSTEIN
510(k) history	25 submissions · 25 cleared · 1984-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k953598/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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