

**K051459 SYSMEX MODEL XE-2100DC AUTOMATED  
HEMATOLOGY ANALYZER**Sep 23, 2005  
113 days to decisionK051459 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k051459/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jun 2, 2005
Decision date	Sep 23, 2005
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sysmex America, Inc.</b>
Location	Mundelein, IL, US
Contact	NINA GAMPERLING
510(k) history	31 submissions · 31 cleared · 2003-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051459/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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