

**K112605 SYSMEX XN-SERIES**Oct 19, 2012  
408 days to decisionK112605 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k112605/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Sep 7, 2011
Decision date	Oct 19, 2012
Days to decision	408 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sysmex America, Inc.</b>
Location	Mundelein, IL, US
Contact	SHARITA BROOKS
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/k112605/> 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 13, 2026