

**K143577 XW-100 Automated Hematology Analyzer, XW QC  
CHECK**Oct 12, 2015  
299 days to decisionK143577 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k143577/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Dec 17, 2014
Decision date	Oct 12, 2015
Days to decision	299 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sysmex America, Inc.</b>
Location	Mundelein, IL, US
Contact	Peter Shearstone
510(k) history	30 submissions · 30 cleared · 2003-2025

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143577/>. 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 May 13, 2026