

**K210346 Sysmex XW-100 Automated Hematology Analyzer**Nov 8, 2022  
638 days to decisionK210346 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k210346/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Counter, Differential Cell (GKZ)
Date received	Feb 8, 2021
Decision date	Nov 8, 2022
Days to decision	638 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210346/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026