

**K172604 XW-100 Automated Hematology Analyzer for CLIA
Waived Use**Nov 6, 2017
68 days to decisionK172604 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k172604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Counter, Differential Cell (GKZ)
Date received	Aug 30, 2017
Decision date	Nov 6, 2017
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sysmex America, Inc.
Location	Mundelein, IL, US
Contact	Michelle Abraham
510(k) history	30 submissions · 30 cleared · 2003-2025

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