

K253212 XR-Series (XR-10, XR-20) Automated Hematology AnalyzersMay 27, 2026
240 days to decisionK253212 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k253212/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Sep 29, 2025
Decision date	May 27, 2026
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sysmex America, Inc.
Location	Mundelein, IL, US
Contact	Yvonne Doswell
510(k) history	31 submissions · 31 cleared · 2003-2026

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