

K250943 Sysmex XR-Series (XR-10) Automated Hematology AnalyzerJun 25, 2025
89 days to decisionK250943 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k250943/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Mar 28, 2025
Decision date	Jun 25, 2025
Days to decision	89 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	30 submissions · 30 cleared · 2003-2025

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