

K251371 Sysmex XR-Series (XR-20) Automated Hematology Analyzer

Jun 25, 2025
54 days to decisionK251371 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k251371/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	May 2, 2025
Decision date	Jun 25, 2025
Days to decision	54 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k251371/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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