

K182389 Sysmex XN-L Automated Hematology AnalyzerJan 25, 2019
143 days to decisionK182389 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k182389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Sep 4, 2018
Decision date	Jan 25, 2019
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182389/> 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 13, 2026