

**K250965 Automated Blood Coagulation Analyzer CN-Series
(CN-6000)**Jun 2, 2025
63 days to decisionK250965 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k250965/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Mar 31, 2025
Decision date	Jun 2, 2025
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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