

**K161312 Sysmex Automated Blood Coagulation Analyzer
CS-2100i**Sep 1, 2016
114 days to decisionK161312 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k161312/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	May 10, 2016
Decision date	Sep 1, 2016
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics Products GmbH
Location	Marburg, DE
Contact	NILS NEUMANN
510(k) history	19 submissions · 18 cleared · 2016-2024

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