

**K150678 Sysmex Automated Blood Coagulation Analyzer  
CS-5100**Jan 11, 2016  
301 days to decisionK150678 · Product code: **JPA** · Hematology  
Source: <https://www.510kdatabase.net/k150678/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Mar 16, 2015
Decision date	Jan 11, 2016
Days to decision	301 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostic Products GmbH</b>
Location	Marburg, DE
Contact	DONNA NOEH
510(k) history	4 submissions · 4 cleared · 2016-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150678/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026