

**K161317 Sysmex Automated Blood Coagulation Analyzer  
CS-5100**

Sep 2, 2016  
114 days to decision

K161317 · Product code: **JPA** · Hematology  
Source: <https://www.510kdatabase.net/k161317/>

**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	May 11, 2016
Decision date	Sep 2, 2016
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics Products GmbH</b>
Location	Marburg, DE
Contact	Nils Neumann
510(k) history	19 submissions · 18 cleared · 2016-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k161317/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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