

K062925 COAGUCHEK XS SYSTEMJan 29, 2007
123 days to decisionK062925 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k062925/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Sep 28, 2006
Decision date	Jan 29, 2007
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	THERESA BUSH
510(k) history	264 submissions · 263 cleared · 1999-2013

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