

**K063823 COAGUCHEK XS PT CONTROLS**Jan 29, 2007  
34 days to decisionK063823 · Product code: **GGN** · Hematology  
Source: <https://www.510kdatabase.net/k063823/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Dec 26, 2006
Decision date	Jan 29, 2007
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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