

**K172913 cobas Factor II and Factor V Test**Jan 12, 2018  
109 days to decisionK172913 · Product code: **NPR** · Hematology  
Source: <https://www.510kdatabase.net/k172913/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Factor Ii G20210a Mutations, Genomic Dna Pcr (NPR)
Date received	Sep 25, 2017
Decision date	Jan 12, 2018
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Molecular Systems, Inc.</b>
Location	Somerville, NJ, US
Contact	Pooja Shah
510(k) history	49 submissions · 46 cleared · 1993-2025

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