

**K033612 FACTOR II (PROTHROMBIN) G20210A KIT**Dec 18, 2003  
31 days to decisionK033612 · Product code: **NPR** · Pathology  
Source: <https://www.510kdatabase.net/k033612/>**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	Nov 17, 2003
Decision date	Dec 18, 2003
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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