

**K051054 VISULIZE FACTOR IX ANTIGEN KIT**Jun 29, 2005  
64 days to decisionK051054 · Product code: **GGP** · Hematology  
Source: <https://www.510kdatabase.net/k051054/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Apr 26, 2005
Decision date	Jun 29, 2005
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Affinity Biologicals, Inc.</b>
Location	Ancaster, Ontario, CA
Contact	DENISE FOULON
510(k) history	5 submissions · 5 cleared · 2005-2016

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