

**K050365 BIOPHEN PROTEIN C5, C2.5, MODELS 221205, 221202**Dec 27, 2005  
316 days to decisionK050365 · Product code: **GGP** · Hematology  
Source: <https://www.510kdatabase.net/k050365/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Feb 14, 2005
Decision date	Dec 27, 2005
Days to decision	316 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hyphen Biomed</b>
Location	Mason, OH, US
Contact	OLA ANDERSON
510(k) history	6 submissions · 6 cleared · 2005-2007

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