

**K061014 ACTALYKE QC KIT, MODELS AQC-HP AND AQC-LP**May 10, 2006  
27 days to decisionK061014 · Product code: **JPA** · Hematology  
Source: <https://www.510kdatabase.net/k061014/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Apr 13, 2006
Decision date	May 10, 2006
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Helena Laboratories</b>
Location	Mchenry, IL, US
Contact	PATRICIA FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

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