

**K921305 GLYCO-TEK AFFINITY COLUMN KIT**Jun 9, 1992  
89 days to decisionK921305 · Product code: **LCP** · Hematology  
Source: <https://www.510kdatabase.net/k921305/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Mar 12, 1992
Decision date	Jun 9, 1992
Days to decision	89 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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