

**K884315 LABILE LYSING REAGENT**Dec 27, 1988  
75 days to decisionK884315 · Product code: **LCP** · Hematology  
Source: <https://www.510kdatabase.net/k884315/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Oct 13, 1988
Decision date	Dec 27, 1988
Days to decision	75 days
Third-party review	No

**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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