

K842689 GLYCO-TEK AFFINITY COLUMNOct 15, 1984
97 days to decisionK842689 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k842689/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jul 10, 1984
Decision date	Oct 15, 1984
Days to decision	97 days
Third-party review	No

APPLICANT

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

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