

K880698 TITAN GEL-PC GLYCO-HEME(TM) SYSTEMMay 6, 1988
74 days to decisionK880698 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k880698/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Feb 22, 1988
Decision date	May 6, 1988
Days to decision	74 days
Third-party review	No

APPLICANT

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

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