

K832087 TITAN GEL GLYCO-HEME SYSTEMAug 24, 1983
57 days to decisionK832087 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k832087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jun 28, 1983
Decision date	Aug 24, 1983
Days to decision	57 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k832087/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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