

K833356 GLYCO-JE,E CPMTRPNov 3, 1983
36 days to decisionK833356 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k833356/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Sep 28, 1983
Decision date	Nov 3, 1983
Days to decision	36 days
Third-party review	No
Other names	-NORMAL/ABNORMAL

APPLICANT

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

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