

K800857 HELENA GLYCOSYLATED HEMOGLOBIN QUIK METHSep 26, 1980
164 days to decisionK800857 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k800857/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Apr 15, 1980
Decision date	Sep 26, 1980
Days to decision	164 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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