

K802233 GLYCOSYLATED HEMOGLOBIN-SMC COLUMNOct 10, 1980
25 days to decisionK802233 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k802233/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Sep 15, 1980
Decision date	Oct 10, 1980
Days to decision	25 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k802233/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026