

**K901414 COLUMNMATE (AUTOMATED COLUMN SYSTEM)
1580, 1581**Jun 15, 1990
81 days to decisionK901414 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k901414/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Mar 26, 1990
Decision date	Jun 15, 1990
Days to decision	81 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k901414/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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