

K921676 COLUMNMATE IIJul 10, 1992
93 days to decisionK921676 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k921676/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Apr 8, 1992
Decision date	Jul 10, 1992
Days to decision	93 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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