

K946274 COLUMNMATE II GHB AFFINITY REGENERABLE COLUMNJul 11, 1995
200 days to decisionK946274 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k946274/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Dec 23, 1994
Decision date	Jul 11, 1995
Days to decision	200 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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