

K961674 ROCHE UNIMATE FRUCTOSAMINE REAGENTSep 27, 1996
149 days to decisionK961674 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k961674/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	May 1, 1996
Decision date	Sep 27, 1996
Days to decision	149 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	MARIA FEIJOO
510(k) history	296 submissions · 296 cleared · 1983-1999

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