

K023654 GLYCA-DIRECT FRUCTOSAMINEMay 2, 2003
184 days to decisionK023654 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k023654/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Oct 30, 2002
Decision date	May 2, 2003
Days to decision	184 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Polymedco, Inc.
Location	Cortlandt Manor, NY, US
Contact	HELEN LANDICHO
510(k) history	19 submissions · 19 cleared · 1992-2011

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