

K131307 ADVIA CHEMISTRY FRUCTOSAMINE ASSAY, ADVIA CHEMISTRY FRUCTOSAMINE CALIBRATORJan 24, 2014
262 days to decisionK131307 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k131307/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	May 7, 2013
Decision date	Jan 24, 2014
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	KIRA GORDON
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

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