

**K090413 A1CNOW+ (10 TEST KIT, PROFESSIONAL USE)
MODEL 3024, A1CNOW+(20 TEST KIT, PROFESSIONAL USE)
MODEL 3021, A1CNOW SELF CHEC**May 14, 2009
85 days to decisionK090413 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k090413/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Feb 18, 2009
Decision date	May 14, 2009
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Healthcare, LLC
Location	New York, NY, US
Contact	CATHY PETERS
510(k) history	46 submissions · 46 cleared · 2003-2018

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