

**K130860 VARIANT II HEMOGLOBIN A1C PROGRAM (NEW),
VARIANT II HEMOGLOBIN TESTING SYSTEM WITH CDM
SOFTWARE, CDM SOFTWARE**Apr 25, 2013
28 days to decisionK130860 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k130860/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Mar 28, 2013
Decision date	Apr 25, 2013
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Rad Laboratories, Inc., Clinical Systems Divis
Location	Hercules, CA, US
Contact	EBONY MCKINNIES
510(k) history	3 submissions · 3 cleared · 2012-2013

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