

**K063643 MODIFICATION TO VARIANT II: HEMOGLOBIN A1C PROGRAM, BETA-THALASSEMIA SHORT PROGRAM AND TOTAL GHB PROGRAM**Dec 27, 2006  
20 days to decisionK063643 · Product code: **LCP** · Chemistry  
Source: <https://www.510kdatabase.net/k063643/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Dec 7, 2006
Decision date	Dec 27, 2006
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bio-Rad Laboratories Inc., Clinical Systems Divisi</b>
Location	Hercules, CA, US
Contact	JACKIE BUCKLEY
510(k) history	3 submissions · 3 cleared · 2006-2008

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