

K070819 VARIANT II TURBO LINK HEMOGLOBIN A1C PROGRAM, AND VARIANT II TURBO LINK HEMOGLOBIN TESTING WITH MODEL, 270-2716,Jun 25, 2007
91 days to decisionK070819 · Product code: **LCP** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Mar 26, 2007
Decision date	Jun 25, 2007
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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