

**K011933 GLYCOSAL II HBA 1C TEST**Nov 2, 2001  
135 days to decisionK011933 · Product code: **LCP** · Chemistry  
Source: <https://www.510kdatabase.net/k011933/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jun 20, 2001
Decision date	Nov 2, 2001
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Provalis Diagnostics , Ltd.</b>
Location	Rockville, MD, US
Contact	THOMAS M TSAKERIS
510(k) history	3 submissions · 3 cleared · 2000-2004

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