

K001392 GLYCOSAL HBA1C TESTAug 21, 2000
110 days to decisionK001392 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k001392/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	May 3, 2000
Decision date	Aug 21, 2000
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Provalis Diagnostics , Ltd.
Location	Rockville, MD, US
Contact	TOM TSAKERIS
510(k) history	3 submissions · 3 cleared · 2000-2004

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