

K121366 HEMOCUE HBA1C 501Sep 7, 2012
123 days to decisionK121366 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k121366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	May 7, 2012
Decision date	Sep 7, 2012
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Infopia Co, Ltd.
Location	Anyang Kvunggi, KR
Contact	MARIA F GRIFFIN
510(k) history	20 submissions · 20 cleared · 2005-2016

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