

K050574 AFINION HBALCJul 22, 2005
137 days to decisionK050574 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k050574/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Mar 7, 2005
Decision date	Jul 22, 2005
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Axis-Shield Poc AS
Location	San Diego, CA, US
Contact	RONALD G LEONARDI
510(k) history	4 submissions · 4 cleared · 2005-2014

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