

K053411 DRI HEMOGLOBIN A1C ASSAY AND CALIBRATORSFeb 3, 2006
58 days to decisionK053411 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k053411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Dec 7, 2005
Decision date	Feb 3, 2006
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Microgenics Corp.
Location	Concord, CA, US
Contact	TONY C LAM
510(k) history	107 submissions · 106 cleared · 1985-2013

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