

K050178 HBA1C ENZYMATIC ASSAYJun 28, 2005
153 days to decisionK050178 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k050178/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jan 26, 2005
Decision date	Jun 28, 2005
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	General Atomics
Location	San Diego, CA, US
Contact	HUAN TRAN
Website	http://www.ga.com
510(k) history	6 submissions · 6 cleared · 2003-2009

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