

K130014 A1C GEAR SYSTEMApr 4, 2014
457 days to decisionK130014 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k130014/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jan 2, 2013
Decision date	Apr 4, 2014
Days to decision	457 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sakae Corporation
Location	Los Angeles, CA, US
Contact	ERICA B AMMIRATI
510(k) history	2 submissions · 2 cleared · 2014-2014

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