

K142789 A1c iGear SystemDec 16, 2014
81 days to decisionK142789 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k142789/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Sep 26, 2014
Decision date	Dec 16, 2014
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142789/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 5, 2026