

**K142689 GAL-1F Blood Glucose Monitoring System, GAL-1F Pro Blood Glucose Monitoring System**

Aug 6, 2015  
318 days to decision

K142689 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k142689/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Sep 22, 2014
Decision date	Aug 6, 2015
Days to decision	318 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Apex BioTechnology Corp.</b>
Location	Plymouth, MN, US
Contact	Hsue-mei Lee
510(k) history	35 submissions · 35 cleared · 2001-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k142689/> 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 4, 2026