

**K011233 MODIFICATION TO GLUCOSURE BGM SYSTEM,
MODEL 221100**May 18, 2001
25 days to decisionK011233 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k011233/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Apr 23, 2001
Decision date	May 18, 2001
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Apex BioTechnology Corp.
Location	Plymouth, MN, US
Contact	BRUCE A MACFARLANE
510(k) history	35 submissions · 35 cleared · 2001-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011233/> 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 28, 2026