

K113208 GAL-1A BLOOD GLUCOSE MONITORING SYSTEMJan 26, 2012
86 days to decisionK113208 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k113208/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Nov 1, 2011
Decision date	Jan 26, 2012
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Apex BioTechnology Corp.
Location	Plymouth, MN, US
Contact	HSUE-MEI LEE
510(k) history	35 submissions · 35 cleared · 2001-2025

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