

K002624 GLUCOSMART BLOOD GLUCOSE MONITORING SYSTEMJan 22, 2001
152 days to decisionK002624 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k002624/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Aug 23, 2000
Decision date	Jan 22, 2001
Days to decision	152 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k002624/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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