

K052121 GEM PREMIER 3000Oct 21, 2005
77 days to decisionK052121 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k052121/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Aug 5, 2005
Decision date	Oct 21, 2005
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Instrumentation Laboratory CO
Location	Mchenry, IL, US
Contact	CAROL MARBLE
510(k) history	321 submissions · 320 cleared · 1976-2023

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