

K223090 GEM Premier ChemSTATJan 27, 2023
119 days to decisionK223090 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k223090/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Sep 30, 2022
Decision date	Jan 27, 2023
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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