

K183546 GEM Premier ChemSTATFeb 16, 2019
58 days to decisionK183546 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k183546/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Dec 20, 2018
Decision date	Feb 16, 2019
Days to decision	58 days
Third-party review	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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