

**K160402 GEM Premier 5000 (Measured Parameters:Glucose, Lactate and Total Bilirubin)**Dec 14, 2016  
306 days to decisionK160402 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k160402/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Feb 12, 2016
Decision date	Dec 14, 2016
Days to decision	306 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Instrumentation Laboratory CO</b>
Location	Mchenry, IL, US
Contact	Carol Murble
510(k) history	321 submissions · 320 cleared · 1976-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160402/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 2, 2026