

**K010520 GEM PREMIER 3000- ADDITION OF GLUCOSE AND LACTATE AS NEW PARAMETERS**May 7, 2001  
74 days to decisionK010520 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k010520/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Feb 22, 2001
Decision date	May 7, 2001
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010520/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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