

**K200349 Stat Profile Prime Plus Analyzer System**Mar 13, 2020  
30 days to decisionK200349 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k200349/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Feb 12, 2020
Decision date	Mar 13, 2020
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nova Biomedical Corporation</b>
Location	Waltham, MA, US
Contact	Rachel Gilbert
510(k) history	40 submissions · 40 cleared · 2011-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200349/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026