

**K203549 Nova Primary Glucose Analyzer System**Oct 18, 2022  
683 days to decisionK203549 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k203549/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Dec 4, 2020
Decision date	Oct 18, 2022
Days to decision	683 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/k203549/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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