

**K221900 Stat Profile Prime Plus Analyzer System**Sep 29, 2023  
456 days to decisionK221900 · Product code: **CHL** · Chemistry  
Source: <https://www.510kdatabase.net/k221900/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode Measurement, Blood-gases (pco2, Po2) And Blood Ph (CHL)
Date received	Jun 30, 2022
Decision date	Sep 29, 2023
Days to decision	456 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	Sharvari Nayak
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/k221900/> 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 May 13, 2026