

K180340 Stat Profile Prime Plus Analyzer SystemSep 26, 2018
231 days to decisionK180340 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k180340/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Feb 7, 2018
Decision date	Sep 26, 2018
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nova Biomedical Corporation
Location	Waltham, MA, US
Contact	Adam Heroux
510(k) history	40 submissions · 40 cleared · 2011-2026

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