

K193246 Stat Profile Prime Plus Analyzer SystemJan 24, 2020
60 days to decisionK193246 · Product code: **CHL** · Chemistry
Source: <https://www.510kdatabase.net/k193246/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode Measurement, Blood-gases (pco2, Po2) And Blood Ph (CHL)
Date received	Nov 25, 2019
Decision date	Jan 24, 2020
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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