

K173797 Stat Profile Prime Plus Analyzer SystemJul 17, 2018
215 days to decisionK173797 · Product code: **CHL** · Chemistry
Source: <https://www.510kdatabase.net/k173797/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode Measurement, Blood-gases (pco2, Po2) And Blood Ph (CHL)
Date received	Dec 14, 2017
Decision date	Jul 17, 2018
Days to decision	215 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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