

K191365 Stat Profile Prime ES Comp Plus Analyzer SystemJul 19, 2019
58 days to decisionK191365 · Product code: **JGS** · Chemistry
Source: <https://www.510kdatabase.net/k191365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Specific, Sodium (JGS)
Date received	May 22, 2019
Decision date	Jul 19, 2019
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191365/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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