

K142220 Stat Profile Prime ABG Analyzer System (incl. Controls, Calibrators)

Oct 17, 2014
66 days to decision

K142220 · Product code: **CHL** · Chemistry
Source: <https://www.510kdatabase.net/k142220/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode Measurement, Blood-gases (pco2, Po2) And Blood Ph (CHL)
Date received	Aug 12, 2014
Decision date	Oct 17, 2014
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nova Biomedical Corporation
Location	Waltham, MA, US
Contact	Paul W. MacDonald
510(k) history	40 submissions · 40 cleared · 2011-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k142220/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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