

K171059 Nova StatSensor Creatinine Hospital Meter SystemMay 26, 2017
46 days to decisionK171059 · Product code: **CGL** · Chemistry
Source: <https://www.510kdatabase.net/k171059/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Ion Based, Enzymatic, Creatinine (CGL)
Date received	Apr 10, 2017
Decision date	May 26, 2017
Days to decision	46 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

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