

K150461 StatStrip Xpress Glucose Hospital Meter SystemMay 20, 2015
86 days to decisionK150461 · Product code: **PZI** · Chemistry
Source: <https://www.510kdatabase.net/k150461/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prescription Use Blood Glucose Meter For Near-patient Testing (PZI)
Date received	Feb 23, 2015
Decision date	May 20, 2015
Days to decision	86 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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