

K163490 StatStrip Xpress 2 Glucose Hospital Meter SystemJan 6, 2017
25 days to decisionK163490 · Product code: **PZI** · Chemistry
Source: <https://www.510kdatabase.net/k163490/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prescription Use Blood Glucose Meter For Near-patient Testing (PZI)
Date received	Dec 12, 2016
Decision date	Jan 6, 2017
Days to decision	25 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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