

K152986 StatStrip Xpress 2 Glucose Hospital Meter SystemJan 27, 2016
110 days to decisionK152986 · Product code: **PZI** · Chemistry
Source: <https://www.510kdatabase.net/k152986/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prescription Use Blood Glucose Meter For Near-patient Testing (PZI)
Date received	Oct 9, 2015
Decision date	Jan 27, 2016
Days to decision	110 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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