

# K182549 StatStrip Xpress 2 Glucose Hospital Meter System

Dec 13, 2018  
87 days to decision

K182549 · Product code: **PZI** · Chemistry  
Source: <https://www.510kdatabase.net/k182549/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Prescription Use Blood Glucose Meter For Near-patient Testing (PZI)
Date received	Sep 17, 2018
Decision date	Dec 13, 2018
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Nova Biomedical Corporation</b>
Location	Waltham, MA, US
Contact	Khushboo Surendran
510(k) history	40 submissions · 40 cleared · 2011-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k182549/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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