

**K181043 StatStrip Glucose Hospital Meter System**Jul 12, 2018  
84 days to decisionK181043 · Product code: **PZI** · Chemistry  
Source: <https://www.510kdatabase.net/k181043/>**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	Apr 19, 2018
Decision date	Jul 12, 2018
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nova Biomedical Corporation</b>
Location	Waltham, MA, US
Contact	John Mchale
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/k181043/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 30, 2026