

K182552 StatStrip Xpress Glucose Hospital Meter SystemDec 13, 2018
87 days to decisionK182552 · Product code: **PZI** · Chemistry
Source: <https://www.510kdatabase.net/k182552/>**SUBMISSION DETAILS**

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

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

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