

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION MEMORANDUM  
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

**A. 510(k) Number:**

k160156

**B. Purpose for Submission:**

This submission seeks an Over-The-Counter (OTC) clearance and new trade name (StatStrip Xpress Blood Glucose Monitoring System) for the previously cleared StatStrip Xpress Glucose Hospital Meter System; k150461. This OTC system uses StatStrip Xpress Glucose Test Strips which were previously cleared in k060345 (as Nova StatStrip Glucose Test Strips) and StatStrip Xpress Glucose Control Solutions which were previously cleared in k0603821 and k060345 (as Nova StatStrip Control Solutions).

**C. Measurand:**

Fresh capillary whole blood glucose from the fingertip

**D. Type of Test:**

Quantitative, amperometric assay (Glucose Oxidase)

**E. Applicant:**

Nova Biomedical Corporation

**F. Proprietary and Established Names:**

StatStrip Xpress Blood Glucose Monitoring System

**G. Regulatory Information:**

1. Regulation section:

21 CFR §862.1345, Glucose test system

21 CFR §862.1660, Quality Control Material (Assayed and Unassayed)

2. Classification:

Class II

Class I, reserved

3. Product code:

NBW, System, Test, Blood Glucose, Over The Counter

CGA, Glucose Oxidase, Glucose

JJX, Single (Specified) Analyte Controls (Assayed and Unassayed))

4. Panel:

Clinical Chemistry, 75

**H. Intended Use:**

1. Intended use(s):

See indication(s) for use below.

2. Indication(s) for use:

The StatStrip Xpress Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip. It is intended for single-patient home use and should not be shared. It is intended for self-testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on neonates.

The StatStrip Xpress Blood Glucose Monitoring System comprises the StatStrip Xpress Blood Glucose Monitor, StatStrip Xpress Glucose Test Strips, and StatStrip Xpress Glucose Control Solutions. The StatStrip Xpress Glucose Control Solutions are intended for use with the StatStrip Xpress Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results. There are three levels of controls, (Level 1, 2, and 3).

The StatStrip Xpress Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use).

3. Special conditions for use statement(s):

- Critically ill patients should not be tested with this device.

- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Incorrect result may occur in individuals who are dehydrated.
- The system should not be used to test neonates.
- Do not reuse; each Test Strip is for single use only.
- Do not test samples other than fresh capillary whole blood obtained from the fingertip.
- Do not use at altitudes above 15,000 feet (4572 meters) above sea level.
- Do not use when humidity is higher than 90% and lower than 10%, as extremes in humidity may affect results.
- Do not use when Hematocrit is outside the acceptable Hematocrit range for testing of 20% to 65%.
- Not intended for the diagnosis or screening of diabetes.
- For single-patient use only.

4. Special instrument requirements:

StatStrip Xpress Blood Glucose Monitor

**I. Device Description:**

The StatStrip Xpress Blood Glucose Monitoring System consists of a hand held StatStrip Xpress Blood Glucose Monitor, StatStrip Xpress Glucose Test Strips, StatStrip Xpress Glucose Control Solutions (Levels 1, 2, and 3), lancing device, lancets, warranty card, Quick reference guide, carrying case, battery, and Owner’s guide. The system is for self-testing.

The StatStrip Xpress Glucose Control Solutions (Levels 1, 2, and 3), previously cleared in k060345 as Nova StatStrip Control Solutions, are to be used with the StatStrip Xpress Blood Glucose Monitoring System. Level 2 control is included in the kit. All control levels are available separately for purchase.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Nova Max Blood Glucose Monitoring System

2. Predicate 510(k) number(s):

k070255

3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Candidate Device k160156 StatStrip Xpress Blood Glucose Monitoring System</b>	<b>Predicate Device k070255 Nova Max Blood Glucose Monitoring System</b>
Intended Use/Indications for Use:	Intended to be used for the quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Test Principle	Electrochemical biosensor, amperometric	Same
Enzyme	Glucose Oxidase	Same
Meter coding	Automatic, no Calibration Code	Same
Test results	mg/dL, plasma equivalent values	Same
Data storage	400 test results	Same
Reportable range	20 to 600 mg/dL	same

<b>Differences</b>		
<b>Item</b>	<b>Candidate Device k160156 StatStrip Xpress Blood Glucose Monitoring System</b>	<b>Predicate Device k070255 Nova Max Blood Glucose Monitoring System</b>
Specimen type	Fresh capillary whole blood from fingertip	Fresh capillary whole blood from fingertip, palm, and forearm.
Test time	6 seconds	5 seconds
Test strip design	4 wells	2 wells
Hematocrit range	20% to 65%	25% to 60%
Sample volume	1.2 µL	0.3 µL
Glucose Control Solutions	StatStrip Xpress Glucose Control Solutions.  Liquid; Three levels labeled as Level 1, 2, and 3.	Nova Max Glucose Control Solutions.  Liquid; Three levels labeled as Low, Normal, and High.

**K. Standard/Guidance Document Referenced (if applicable):**

No applicable standard was cited.

**L. Test Principle:**

The StatStrip Xpress Blood Glucose Monitoring System measures glucose levels using disposable test strips and a handheld meter. The test strip contains a flow channel to draw blood by capillary action into a biosensor measurement zone. The sensor comprises an enzyme (Glucose oxidase) that oxidizes glucose present in the blood sample. The sensor also contains an electron shuttle to re-generate, by oxidation, the active form of the enzyme. The meter applies a low electrical voltage to the sensor electrodes and measures a change in current caused by the electrochemical oxidation of the electron shuttle.

**M. Performance Characteristics (if/when applicable):**

This submission seeks an Over-The-Counter clearance and new trade name (StatStrip Xpress Blood Glucose Monitoring System) for the previously cleared StatStrip Xpress Glucose Hospital Meter System; k150461. The proposed device uses identical technology, measurement algorithm, user workflow, test strips as the predicate, the StatStrip Glucose Hospital Meter System (originally cleared in k060345 and modified in k063821, k070960, k132121 and k150461). Bench studies to collect performance data relied on these previously cleared devices, which are cited, as appropriate in each section.

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-run and intermediate precision were established in k060345.

b. *Linearity/assay reportable range:*

Linearity and reportable range were established in k060345.

The reportable range for the StatStrip Xpress Blood Glucose Monitoring System is 20 to 600 mg/dL.

Readings outside of reportable range:

Bench studies and software verification studies were provided to demonstrate that if a glucose measurement is less than 20 mg/dL, the result is flagged and a 'LO' indicator is displayed. If a glucose measurement exceeds 600 mg/dL, the result is flagged and a 'HI' indicator is displayed.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability:

The StatStrip Xpress Blood Glucose Monitoring System is traceable to NIST Standard SRM917B.

Test Strip Stability:

Stability protocols and acceptance criteria for the StatStrip Xpress Blood Glucose Test Strips were evaluated in k060345 and found to be acceptable. The claimed closed-vial stability is 24 months at 34-86°F and 10-90% RH. The claimed open-vial stability is 6 months when stored at the recommended storage temperatures 34-86°F and 10-90% RH or until the expiration date printed on the label, whichever comes first.

Controls Stability:

Stability protocols and acceptance criteria for the StatStrip Xpress Glucose Control Solutions were reviewed in k060345 and found to be acceptable. The control solutions have a 24 month shelf-life from the date of manufacture when stored at 59-86°F. The claimed open-vial stability is 3 months when stored within the recommended storage temperature range of 59-86°F.

d. *Detection limit:*

See linearity study in Section M1b above.

e. *Analytical specificity:*

Potential interference from some common endogenous and exogenous substances was established in k132121.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

Method comparison studies were established in k060345.

b. *Matrix comparison:*

Not applicable. Capillary whole blood is the only indicated matrix.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable.

b. *Clinical specificity:*

Not applicable.

c. *Other clinical supportive data (when a. and b. are not applicable):*

User performance study:

To assess the performance of the StatStrip Xpress Blood Glucose Monitoring System in the hands of the intended users, a lay user study was conducted with 360 subjects. Each participant self-tested their blood glucose level unassisted and was given only the instructions and training materials routinely provided with the system. The blood glucose results obtained from the fingerstick were compared to a reference method (YSI 2300 STAT Plus Glucose & Lactate Analyzer). The range of glucose concentrations across all subjects was 48 to 434 mg/dL according to the reference method. The results from this study are summarized below:

Glucose concentrations < 75 mg/dL:

<b>Within ± 5 mg/dL</b>	<b>Within ± 10 mg/dL</b>	<b>Within ± 15 mg/dL</b>
6/14 (43%)	12/14 (86%)	14/14 (100%)

Glucose concentrations ≥ 75 mg/dL:

<b>Within ± 5%</b>	<b>Within ± 10%</b>	<b>Within ± 15%</b>	<b>Within ± 20%</b>
110/346 (32%)	310/346 (90%)	338/346 (98%)	346/346 (100%)

The method accuracy was further analyzed by linear regression analysis. The results are given below.

<b>Linear regression equation</b>	<b>R<sup>2</sup></b>
$y = 0.969x + 4.01$	0.991

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The StatStrip Xpress Blood Glucose Test Strips package insert includes the following:

The normal fasting adult blood Glucose range for a person without diabetes is less than 100 mg/dL. One to two hours after meals, normal blood Glucose levels should be less than 140 mg/dL.

From: American Diabetes Association, Standards of Medical Care in Diabetes. Diabetes Care, Vol 38, Supplement 1. January 2015.

**N. Instrument Name:**

StatStrip Xpress Blood Glucose Monitor

**O. System Descriptions:**

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes  or No

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes  or No

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes  or No

3. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as collected.

4. Specimen Sampling and Handling:

The glucose test is intended to be used with fresh capillary whole blood from the fingertip. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

No user entered coding or calibration is required for this device.

6. Quality Control:

StatStrip Xpress Glucose Control Solutions (Level 1, Level 2, and Level 3) are available with this system. Level 2 control is included in the kit. All control levels are available separately for purchase using the contact information provided in the user guide.

Instructions for how to use the control solutions are provided in the user manual and the ranges are provided on the test strip vial labels. When running a control, the user identifies the sample as a control and the level (i.e. Level 1, 2, or 3) through entries on the meter's user interface arrow buttons. The control results are automatically stored into memory.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:**

1. Hematocrit Study: As established in k060345 to support the claimed hematocrit range of 20-65%.
2. Altitude study: As established in k060345. There is no significant affect of altitude up to 15,000 feet (4500 meters) above sea level.
3. Temperature and Humidity Study: As established in k060345 to support the claimed operating condition range of 59°F -104°F and 10-90% relative humidity. The meter displays an error code and no result will be obtained when the meter is outside of this temperature range.
4. Sample Volume Study: The sponsor performed a study to validate the test strip sample volume requirement for the StatStrip Xpress Blood Glucose Monitoring System. Blood glucose samples (71, 122, and 305 mg/dL) were tested at five sample volumes (0.9, 1.0, 1.1, 1.2, and 1.3  $\mu$ L). The glucose concentrations were compared a reference method (YSI 2300 STAT Plus Glucose & Lactate Analyzer). The sample volume study results support the claimed sample volume of 1.2  $\mu$ L and the error code for insufficient sample volume.
5. Infection Control Studies: The StatStrip Xpress Blood Glucose Monitoring System is intended for single-patient use only. Disinfection efficacy studies were performed (k100602 and k150461) on the external materials of the meter by an outside commercial testing service and demonstrated complete inactivation of live Hepatitis B virus with Clorox Germicidal Wipes, EPA registration # 67619-12. Robustness testing was performed by the sponsor (k150461) demonstrating that there was no change in performance or in the external materials of the meter after 10,950 cleaning and 10,950 disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 3 years of device use. The subject device labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. Electromagnetic Compatibility: The sponsor provided documentation certifying that acceptable electromagnetic testing (EMC) had been performed and the StatStrip Xpress Blood Glucose Monitoring System was found compliant (k070960).
7. Readability Evaluation: The readability of the Owner's Manual, Test Strip package insert, Control package insert, and Quick Reference Guide were evaluated using a Flesch-Kincaid analysis and were found to be at an 8<sup>th</sup> grade reading level or less.
8. Customer service is available Monday through Saturday 9:00 am to 5:30 pm EST by calling 1-800-681-7390.

**Q. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**R. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.