

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

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

k150461

**B. Purpose for Submission:**

Modified device to expand the indications for use of venous and arterial blood samples for use in all hospitalized patients.

**C. Measurand:**

Glucose in fresh capillary whole blood from the fingertip, venous whole blood, arterial whole blood, neonatal heelstick blood and neonatal arterial whole blood

**D. Type of Test:**

Quantitative amperometric assay, glucose oxidase

**E. Applicant:**

Nova Biomedical Corporation

**F. Proprietary and Established Names:**

StatStrip Xpress Glucose Hospital Meter System

**G. Regulatory Information:**

1. Regulation section:  
21CFR 862.1345, Glucose test system
2. Classification:  
Class II
3. Product code:  
CGA, Glucose Oxidase, Glucose
4. Panel:  
Clinical Chemistry, CH (75)

## H. Intended Use:

1. Intended use(s):

See indication(s) for use below.

2. Indication(s) for use:

The StatStrip Xpress Glucose Hospital Meter System is intended for point-of-care, in vitro diagnostic, multiple patient use for the quantitative determination of glucose in capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood, and neonate heel stick specimens.

The StatStrip Xpress Glucose Hospital Meter System is also intended for use in the quantitative determination of glucose in venous whole blood, arterial whole blood, neonatal heel stick and neonatal arterial whole blood samples throughout all hospital and all professional healthcare settings.

The system should only be used with single-use, auto-disabling lancing devices when performing a capillary finger stick or neonate heel stick.

It is not intended for use with neonate cord blood specimens.

It is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.

3. Special conditions for use statement(s):

For prescription use only

For in vitro diagnostic use only

Capillary whole blood specimens (e.g. obtained by fingerstick) should not be used in patients receiving intensive medical intervention/therapy because of the potential for preanalytical collection error and specifically in patients with decreased peripheral blood flow, as it may not reflect the true physiological state. Examples include, but are not limited to, severe hypotension, shock, hyperosmolar-hyperglycemia (with or without ketosis) and severe dehydration.

The system has not been evaluated for use with neonate venous blood.

Temperature and humidity extremes - Test results may be inaccurate when test strips are stored outside of the storage and handling conditions.

Use of the system outside of traditional healthcare settings (e.g., ambulance services) is limited to the following ambient temperature range: 59-104°F (15- 40°C). Outside of this

range, the system will generate an E-2 Temperature Error code and a blood glucose result will not be obtained.

Altitudes above 15,000 feet (4500 meters) above sea level have not been evaluated.

Specimens - Only fresh whole blood or whole blood collected in lithium heparin collection devices should be used for arterial and venous specimens.

Fluoride, EDTA, Sodium, and Ammonium blood collection devices should not be used.

Use only whole blood. Do not use serum or plasma.

Should only be used with single-use, auto-disabling lancing devices

4. Special instrument requirements:

StatStrip Express Glucose Hospital Meter

**I. Device Description:**

The Nova Biomedical StatStrip Xpress Glucose Hospital Meter System consists of a hand held StatStrip Xpress Glucose Hospital Meter, StatStrip Glucose Hospital Meter Test Strips, StatStrip Glucose Control Solutions (Levels 1, 2, 3, sold separately), StatStrip Glucose Linearity Kit solutions (Levels 1, 2, 3, 4, 5, sold separately) and Instructions for Use Manual. The test strip contains a reagent (glucose oxidase) that reacts with the glucose in the test sample. The sample is applied to a reagent test strip, which is then analyzed with the meter. The test strip contains glucose oxidase and glucose dehydrogenase, which reacts with the glucose in the test sample. The reaction produces an electrical current which is proportional to the amount of glucose in the sample, and the electrical current is detected by the meter and displayed to the user as a glucose value.

Each StatStrip Glucose Hospital Meter Test Strip contains glucose oxidase (*Aspergillus* sp.) >1.0 IU, mediator and buffer >20 µg, and other nonreactive substances.

Three levels of control solutions (Level 1, Level 2, Level 3) and five levels of linearity solutions (Level 1, Level 2, Level 3, Level 4, Level 5) are available for use with the StatStrip Xpress Glucose Hospital Meter System and were previously cleared in k060345.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

StatStrip Glucose Hospital Meter System

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

k132121

3. Comparison with predicate:

<b>Similarities</b>		
Item	Predicate Device: StatStrip Glucose Hospital Meter System (k132121)	Candidate Device: StatStrip Xpress Glucose Hospital Meter System
Indications for Use	For the quantitative determination of glucose in capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood and neonate heel stick specimens. Also for the quantitative determination of glucose in venous whole blood, arterial whole blood, neonatal heel stick, and neonatal arterial whole blood throughout all hospital and all professional healthcare settings.	Same
Enzyme	Glucose Oxidase	Same
Operating Principle	Electrochemical biosensor, amperometric	Same
Sample type	Capillary whole blood (finger stick), venous whole blood, arterial whole blood, neonate heel stick, and neonate arterial whole blood.  Venous whole blood, arterial whole blood, neonatal heel stick, and neonatal arterial whole blood samples throughout all hospital and all professional	Same
Measuring range	10-600 mg/dL	Same
Hematocrit range	20-65%	Same
Reported output	mg/dL	Same
Minimal Sample Volume	1.2µL	Same
Time to Result	~ 6 seconds	Same
Calibration	Automatic, no Calibration Code	Same
Quality Control	3 levels	Same
Linearity	5 levels	Same
Handheld?	Yes	Same

<b>Differences</b>		
<b>Item</b>	<b>Predicate Device StatStrip Glucose Hospital Meter (k132121)</b>	<b>Candidate Device</b>
Data storage	1000 patient and 200 QC test results	400 test results
Barcode	Yes	No
Power source	Rechargeable 3.7 volt Lithium battery	Disposable 3v DC Li coin cell battery
Dimensions	6.0x3.25x1.8 in (153x82.5x46 mm)	3.6x2.3x0.9 in (91.4x58.4x22.9 mm)
Weight	0.6 lb (266 grams)	0.17 lb (75grams)
Network Connectivity	Yes (via docking station)	No

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

None.

**L. Test Principle:**

The Nova StatStrip Xpress Glucose Hospital Meter System measures glucose levels using disposable test strips and a handheld meter. The test principle is based on electrochemical biosensor technology and capillary action. Blood is applied to the reagent portion of a test strip via capillary action. The system quantitatively measure blood glucose levels using glucose oxidase enzyme chemistry. The electrons generated during a reaction in the reagent portion of the test strip are transferred from the blood to test strip electrodes. The magnitude of the resultant current in the test strip electrodes is proportional to the concentration of glucose in the specimen and the signal is converted into a readout displayed on the meter.

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

The StatStrip Xpress Glucose Hospital Meter System that is the subject of this submission is identical to the device cleared in k070960. Performance of the StatStrip Xpress Glucose Hospital Meter System cleared in k070960 was established in k060345 and k063821. The StatStrip Xpress Glucose Hospital Meter System uses identical technology, software measurement algorithm, user workflow, test strips, quality control, and linearity solution as the predicate device, the StatStrip Glucose Hospital Meter System (originally cleared in k060345 and modified in k063821 and k132121). This submission was for the expansion of the intended use population for the StatStrip Xpress Glucose Hospital Meter System to add the use of venous whole blood, arterial whole blood, neonatal heel stick and neonatal arterial whole blood samples throughout all hospital and all professional healthcare settings.

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 k063821.

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

Traceability

Traceability is as described in k060345.

Stability and Expected Values

*Test Strips:* Stability protocols for the test strips were evaluated in k060345. The claimed closed-vial stability is 24 months at 33-86°F and 10-90% RH. The claimed open-vial stability is 180 days when stored at the recommended storage temperatures 33-86°F and 10-90% RH or until the expiration date printed on the label, whichever comes first. The labeling instructs the users not to freeze the test strips.

*Control Solutions:* The three control solutions compatible for use with the current device (StatStrip Glucose Control Solutions: Levels 1- 3) were previously cleared, and stability and value assignment was established in k060345. The ranges for each control solution are provided on the test strip vial label.

*Linearity Solutions:* The five linearity solutions compatible for use with the current device (StatStrip Glucose Linearity Solutions, Levels 1-5) were previously cleared, and stability and value assignment protocols were reviewed and determined to be adequate in k060345. The ranges for each linearity solution are provided on the linearity solution vial label.

*d. Detection limit:*

The reportable range for the StatStrip Xpress Glucose Hospital Meter System is 10 to 600 mg/dL. This range was verified by a linearity study and established in k063821. The meter displays “LO” with glucose values below 10mg/dL, and “HI” with glucose values over 600 mg/dL.

*e. Analytical specificity:*

Potential interference from some common endogenous and exogenous substances was established in k060345. Additional interference testing to support the use of the StatStrip Xpress Glucose Hospital Meter System throughout all hospital and all professional healthcare settings was established in k132121. Potentially interfering substances in the intended use population were also evaluated in a clinical study as part of k132121 (see also Clinical Studies, section M.3.c., below).

*f. Assay cut-off:*

Not applicable

2. Comparison studies:

*a. Method comparison with predicate device:*

Performance for venous whole blood, arterial whole blood and capillary finger stick samples was established in k060345. Performance for neonatal heelstick and neonatal arterial whole blood samples was established in k063821.

*b. Matrix comparison:*

Not applicable.

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):*

The performance of the StatStrip Xpress Glucose Hospital Meter System in hospitalized patients—including potential interference from medications and medical conditions—was established in k132121, in a clinical study performed with 1698 patients throughout 5 hospitals. This study evaluated potential interfering effects of over 250 medical condition subclasses and 8000 medications. No specific medical conditions or medications were determined to have an interfering effect on the device.

## **CLIA WAIVER**

The StatStrip Xpress Glucose Hospital Meter System previously obtained CLIA WAIVER by application on October 30, 2009. Studies performed to support CLIA waiver for this device were reanalyzed to evaluate whether the data would meet new and clinically appropriate Limits of Erroneous Results (LER) and Allowable Total Error (ATE) for the sponsor's new intended use population (all hospitalized patients). The analysis demonstrates that the previous CLIA Waived studies in venous and arterial whole blood meet appropriate waiver standards for hospitalized patients. The percentage of arterial and venous data over the entire measurement range that falls

within the ATE zone is 98.1%. None of the results for any sample type were in the LER zone.

Therefore, the sponsor's CLIA waived status is extended to cover the new intended use claims cleared in this current submission.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The sponsor included the following Expected Values from the literature<sup>1</sup> for normal glucose levels in their test strip labeling:

The normal adult fasting blood glucose range for a non-diabetic person is less than 100 mg/dL (5.55 mmol/L) and less than 140 mg/dL (7.77 mmol/L) 1-2 hours after meals.

<sup>1</sup> American Diabetes Association. Diagnosis and Classification of Diabetes Mellitus. Diabetes Care, Volume 38, Supplement 1, January 2015.

**N. Instrument Name:**

StatStrip Xpress Glucose Hospital Meter System

**O. System Descriptions:**

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings.

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

Yes \_\_\_X\_\_\_ or No \_\_\_\_\_

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

Yes \_\_\_\_\_ or No \_\_\_X\_\_\_

2. Software:

Software documentation was reviewed and found to be adequate in k070960. No changes were made to the software in this submission.

3. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected. The StatStrip Xpress Glucose Hospital Meter stores up to 400 patient test results.

4. Specimen Sampling and Handling:

The glucose test is intended to be used with capillary fingerstick whole blood, arterial whole blood, venous whole blood, neonatal heel stick and neonatal arterial whole blood. The 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:

Three levels of aqueous ready to use glucose control solutions are available with this system (Level 1, Level 2, and Level 3). Control solution testing can be performed by testing a Control Solution sample with the System and marking the test as a Control Solution test using buttons on the meter. Recommendations on when to test the control materials are provided in the labeling. An acceptable range for each control level is printed on the vial label of the control being used.

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

1. **Hematocrit Study:** As established in k060345 and k063821 to support the claimed hematocrit range of 20-65%.
2. **Altitude study:** As established in k060345 to support the use of the device up to 15,000 ft.
3. **Temperature and humidity studies:** As established in k060345 to support the claimed operating condition range of 59°F -104°F and 10-90% relative humidity.
4. **Sample Volume Studies:** As established in k060345 to support the claimed minimal sample volume of 1.2µl.
5. **Infection Control Studies:** The StatStrip Xpress Glucose Hospital Meter System is intended for multiple-patient use. Disinfection efficacy studies were performed 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). The sponsor also demonstrated that there was no change in performance or in the external materials of the meter after 10,950 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 3 years of device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. **Software:** Software documentation was reviewed and demonstrated that the device was developed under appropriate software lifecycle processes.
7. **Electromagnetic Compatibility (EMC) testing:** Certificates of Electromagnetic Compatibility (EMC) as established in k060345.
8. Technical Support is available by calling 1-800-545-6682.

**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.