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

A. 510(k) Number:

k181043

B. Purpose for Submission:

This submission is a Dual 510(k) and CLIA Waiver by Application (Dual Submission) tracked as k181043 and CW180005. This 510(k) is to expand the indications for use for the StatStrip Glucose Hospital Meter System to include capillary whole blood samples for use in all hospitalized patients.

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative amperometric assay, glucose oxidase

E. Applicant:

Nova Biomedical Corporation

F. Proprietary and Established Names:

StatStrip Glucose Hospital Meter System

G. Regulatory Information:

Product Code	Regulation Name	Classification	Regulation Section	Panel
PZI	Glucose Test System	II	21 CFR 862.1345	Clinical Chemistry

H. Intended Use:

1. Intended Use:

See Indications for Use below.

2. Indications for Use:

   The StatStrip 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 throughout all hospital and all professional healthcare settings including patients receiving intensive medical intervention/therapy.

   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
   - 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.
   - 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
   - Caution should be exercised when testing capillary whole blood due to potential pre-analytical variability in capillary specimen collection.
   - A capillary whole blood specimen relies upon an adequate, non-compromised capillary blood flow. The healthcare provider must be aware that a capillary whole blood specimen glucose result may not always be the same as an arterial or a venous whole blood glucose result, especially when the patient's condition is rapidly changing.
   - If a capillary whole blood glucose result is not consistent with a patient's clinical signs and symptoms, glucose testing should be repeated with either an arterial or venous specimen on the StatStrip Glucose Hospital Meter System.

4. Special instrument requirements:

   StatStrip Blood Glucose Hospital Meter

I. Device Description:

The StatStrip Glucose Hospital Meter System (previously cleared under k060345, k063821 and k132121 and k150281) consists of a hand held StatStrip Glucose Hospital meter,

StatStrip Test Strips (sold separately), Nova StatStrip Control Solutions (Levels 1, 2 and 3; sold separately), Nova StatStrip Linearity Test Kit solutions (5 levels; sold separately), docking station, Quick Reference Guide, and User Manual.

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 Glucose Hospital Meter System and were previously cleared in k060345.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Nova StatStrip Glucose Hospital Meter System

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

   k150281

3. Comparison with predicate:

Similarities and Differences		
Item	Predicate Device (k150281)	Candidate Device (k181043)
Indications for Use/Intended Use	Intended 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 for use in determining dysglycemia	Same
Population limitation	Capillary whole blood specimens (e.g. obtained by finger stick) should not be used in patients receiving intensive medical intervention/therapy because of the potential for pre-analytical collection error and specifically in patients with decreased peripheral blood flow, as it may not truly reflect the patient's true physiological state. Examples include, but are not limited to, severe	Cleared for use with capillary fingerstick samples in all hospital patients including those receiving intensive medical intervention/therapy.

Similarities and Differences		
Item	Predicate Device (k150281)	Candidate Device (k181043)
	hypotension, shock, hyper-osmolar-hyperglycemia (with or without ketosis) and severe dehydration.	
Enzyme	Glucose Oxidase	Same
Test Principle	Electro-chemical biosensor	Same
Sample type	Capillary finger stick, venous and arterial whole blood, neonatal arterial whole blood and neonatal heelstick.	Same
Measuring range	10-600 mg/dL	Same
Measuring time	6 sec	Same
Sample volume	1.2 µL	Same
Data storage	1000 Patient Test 200 QC Tests 4000 Operators	Same
Wi-Fi network connectivity	Yes	Same

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

IEC 61010-1:2010, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

EN 60601-1-2:2007, Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests

L. Test Principle:

The Nova StatStrip Hospital Meter System is based on electrochemical biosensor technology and the principle of capillary action. The system quantitatively measures blood glucose levels using glucose oxidase enzyme chemistry. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the resultant current 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):

1. Analytical performance:

   a. Precision/Reproducibility:

   Previously established in k060345.

   b. Linearity/assay reportable range:

   As established in k063821, the reportable range for the Nova StatStrip Glucose Hospital Meter System is 10 to 600 mg/dL.

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

   Traceability to NIST Standard SRM917B, as established in k060345.

   Test Strip:
   Test strip stability protocols and acceptance criteria were evaluated in k060345 and were found to be acceptable to support the claimed shelf life of 24 months at 33-86°F and 10-90% relative humidity (RH) and the claimed open-vial stability of 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.

   d. Detection limit:

   This range was verified by the linearity established in k063821; section M.1.b.

   e. Analytical specificity:

   Potential interference from common endogenous and exogenous substances, as well as in vivo interference, was evaluated in k060345 and k132121.

   f. Assay cut-off:

   Not Applicable.

2. Comparison studies:

   a. Method comparison study
   Performance for capillary finger stick, venous whole blood and arterial whole blood samples from non-hospitalized patients was established in k060345.

   Performance for neonatal heelstick and neonatal arterial samples was established in k063821.

Performance for venous and arterial, neonatal heelsticks and neonatal arterial samples from patients throughout the hospital was established in k132121.

In this submission, additional comparison studies were performed using fingerstick capillary samples at three hospital sites as follows:

Study 1
For Study 1, 568 capillary whole blood fingerstick specimens were obtained from patients within three different critical care units including the cardiovascular intensive care unit (CVICU), medical intensive care unit (MICU), and the operating room (OR). This study included 80 unique patient conditions receiving a total of 3,785 medications representing 17 parent drug classes. All testing with the StatStrip Blood Glucose Hospital Meter (StatStrip Meter) was performed by CLIA waived operators (non-laboratory personnel, typically nursing staff) within each of these three critical care settings. Capillary whole blood glucose results on the StatStrip Meter were compared to matched arterial or venous plasma results obtained on a comparator method, the Roche Cobas Modular P800 Hexokinase System, located in a central laboratory. The glucose ranges of the samples, according to the comparator method, ranged from 74 mg/dL to 379 mg/dL glucose. The results from the capillary fingerstick samples obtained from the StatStrip Hospital Meter compared to the results from the comparator method are summarized below:

Fingertip capillary samples with glucose concentrations <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL	Exceeds ± 15 mg/dL
1/1 (100%)	1/1 (100%)	1/1 (100%)	1/1 (100%)	0/1 (0%)

Fingertip capillary samples with glucose concentrations ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
277/567 (48.9%)	450/567 (79.4%)	484/567 (85.4%)	516/567 (91.0%)	549/567 (96.8%)	18/567 (3.2%)

Study 2
Over 16,000 paired critical care capillary glucose specimens were retrospectively identified and met the following criteria:

Within critical care departments, a capillary fingerstick specimen, and a venous/arterial glucose result were measured at the bedside by a CLIA Waived operator using the BGMS.

Subsequently a plasma glucose test was performed on the same subject on the central laboratory hexokinase method within 15 minutes.

Capillary whole blood glucose results on the StatStrip Meter were compared to matched arterial or venous plasma results obtained on a comparator method, Roche Cobas Modular P800 Hexokinase System. The glucose ranges of the samples, according to the comparator method, ranged from 27 mg/dL to 667 mg/dL glucose. The results from the capillary fingerstick samples obtained from the StatStrip Hospital Meter compared with the results from the comparator method are summarized below:

Fingertip capillary samples with glucose concentrations <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL	Exceeds ± 15 mg/dL
907/1894 (47.9%)	1470/1894 (77.6%)	1614/1894 (85.2%)	1737/1894 (91.7%)	157/1894 (8.3%)

Fingertip capillary samples with glucose concentrations ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 12 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
7473/14884 (50.2%)	11087/14884 (74.5%)	12799/14884 (86.0%)	13712/14884 (92.1%)	14350/14884 (96.4%)	534/14884 (3.6%)

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):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Normal (non-diabetic) adult fasting: Less than 100 mg/dL (5.55 mmol/L) and less than

140 mg/dL (7.77 mmol/L) 1-2 hours after meals.

American Diabetes Association. Classification and Diagnosis of Diabetes: Standards of Medical care in Diabetes. Diabetes Care (2018), Volume 41, Supplement 1.

N. Instrument Name:

Nova StatStrip Glucose Hospital Meter, previously cleared in k150281.

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 ____X____ or No _____

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

   Yes ____X____ or No _____

2. Software:

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

   Yes ___X_____ or No _____

3. Specimen Identification:

   The Nova StatStrip Glucose Hospital Meter memory will store 1000 patient tests, 200 QC tests, and 4000 operators. The meter contains a laser barcode scanner that allows for scanning patient identification information that may also be entered manually.

4. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary fingerstick whole blood, arterial, venous, neonatal heel stick and neonatal arterial. The blood sample is applied directly to the test strip by capillary action.

   The meter stores patient test data, quality control test data, and other information relating to the patient, patient sample, operator, reagents, and meter. Meter setup options relating to authorized operators, reagent lots, quality control preferences, and other operational settings are customizable. Data is transferred bi-directionally between the meter, data docking station, and separate data management system each time a meter is placed in to a data docking station.

5. Calibration:

   The meter does not require the user to input a test strip code or perform any other calibration.

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 pushing the QC key, entering (or scanning) the test strip lot number. 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) Infection Control Studies:
   The device is intended for multiple-patient use. Disinfection efficacy studies were performed (in k132121) on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox Germicidal Wipes, EPA registration # 67619-12 was validated for use with the meter. Robustness studies were also performed by the sponsor (in k132121) demonstrating that there was no change in performance or in the external materials of the modified StatStrip Glucose Hospital Meter after 10,950 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) using the Clorox Germicidal Wipes to simulate 3 years of device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

5) Electromagnetic Compatibility and Electrical Safety:
   Established in k150281.

6) Wireless Data Transmission Test:
   As established in k150281 to support functional use in a hospital environment.

7) Clinical Chemistry and Clinical Toxicology Devices Panel:
A FDA meeting of the Clinical Chemistry and Clinical Toxicology Panel was held on March 30th, 3018, to discuss the benefits and risks of measuring capillary blood using blood glucose meters in patients receiving intensive medical intervention/therapy. The data from the 2 studies above using the Nova StatStrip meter were part of the data presented to the panel. The panel concluded that with respect to the performance data generated in the studies presented during the panel, the benefits outweigh the risk in this patient population receiving intensive medical intervention/therapy.

Q. Proposed Labeling:

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

R. Conclusion:

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