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

A. 510(k) Number:

k150281

B. Purpose for Submission:

Modified device to add wireless (Wi-Fi) connectivity, modify the meter layout and revise the accompanying docking/charging station.

C. Measurand:

Capillary whole blood glucose, venous, arterial, neonate arterial, and neonate heelstick samples.

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:

1. Regulation section:

   21 CFR 862.1345, Glucose test system

2. Classification:

   Class II

3. Product code:

   CGA, Glucose Oxidase, Glucose

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indications for Use below.

2. Indications(s) 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.

The StatStrip 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 pre-analytical 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.

   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 Blood Glucose Hospital Meter

I. Device Description:

The StatStrip Glucose Hospital Meter System, previously cleared under k060345, k063821 and k132121, has been modified in meter layout and to include a wireless (Wi-Fi) connectivity option which provides an additional communication method with a healthcare facility's network system. Additionally, the docking station has been revised to accommodate an additional meter.

The modified system consists of the StatStrip Glucose Hospital meter (with integrated Wi-Fi connection and antenna option), 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), charging station, battery (3.7V lithium), Quick Reference Guide, and User Manual.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Nova StatStrip Glucose Hospital Meter System

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

   K132121

3. Comparison with predicate:

Similarities and Differences		
Item	Predicate Device (k132121)	Candidate Device (k150281)
Brand Name	Nova StatStrip Glucose Hospital Meter System	Same
Indications for Use/Intended 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
Test Principle	Electro-chemical biosensor	Same
Sample type	Capillary finger stick, venous and arterial whole blood, neonatal arterial whole blood and neonatal heelstick. Venous and arterial whole blood, neonatal arterial whole blood, and	Same

Similarities and Differences		
Item	Predicate Device (k132121)	Candidate Device (k150281)
	neonatal heelstick in all hospital and all professional healthcare settings.	
Measuring range	10-600 mg/dL	Same
Measuring time	6 sec	Same
Sample volume	1.2 μL	Same
Control solutions	3 liquid levels	Same
Linearity solutions	5 liquid levels	Same
Data Storage	1000 Patient Test 200 QC Tests 4000 Operators	Same
Wi-Fi network connectivity	None	Yes
Meter dimension and weight	153 mm (6.0 in) x 82.5 mm (3.25 in) x 46 mm (1.8 in) 266 grams (0.6 lb)	146 mm (5.8 in) x 79 mm (3.1 in) x 30 mm (1.18 in) 220 grams (0.49 lb)
Strip ejector button	None	Yes
Docking/Charging Station	single station only	single, dual and quad stations

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

- IEC/EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.
- BS EN 55011:2009+A1:2010: Industrial, scientific and medical equipment - Radio frequency disturbance characteristics - Limits and Methods of Measurement
- 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):

This submission was for adding wireless (Wi-Fi) connectivity and minor modifications to meter layout. The Test Strips, Control Solutions and Linearity Kit Solutions were not modified from the predicate.

1. <u>Analytical performance:</u>

a. Precision/Reproducibility:

As established in k060345

b. Linearity/assay reportable range:

As established in k063821.

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

Traceability was established in k060345.
Control Solutions:
Value Assignment and Stability protocols for the 3 levels of control solutions were evaluated in k060345. The ranges for each control solution are provided on the test strip vial label.

Linearity Solutions:
Value Assignment and Stability protocols for the 5 levels of linearity solutions were evaluated in k060345.

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.

d. Detection limit:

The reportable range for the Nova StatStrip Glucose Hospital Meter System is 10 to 600 mg/dL. 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 with predicate device:

As established in k132121.

In this submission, an additional method comparison study was performed using the modified device by trained technicians who tested 86 native whole blood samples and 14 contrived samples (with glucose concentrations <70 mg/dL or >360 mg/dL) using 3 devices and 3 lots of test strips. All samples were tested in singlicate on the

candidate device an on an YSI 2300 reference analyzer. The results for each of the 3 meter/strip lot tested is displayed below:

System accuracy results vs. YSI for glucose concentrations <75 mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Meter 1	12/13 (92.3%)	13/13 (100%)	13/13 (100%)
Meter 2	10/13 (76.9%)	13/13 (100%)	13/13 (100%)
Meter 3	11/13 (84.6%)	13/13 (100%)	13/13 (100%)

System accuracy results vs. YSI for glucose concentrations ≥75 mg/dL

	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Meter 1	63/87 (72.4%)	87/87 (100%)	87/87 (100%)	87/87 (100%)
Meter 2	53/87 (60.9%)	83/87 (95.4%)	87/87 (100%)	87/87 (100%)
Meter 3	65/87 (74.7%)	83/87 (95.4%)	87/87 (100%)	87/87 (100%)

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. Diabetes Care (2013), Volume 36, Supplement 1.

N. Instrument Name:

Nova StatStrip Glucose Hospital Meter

O. System Description:

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 __X__ or No _____.

2. Software:

   FDA has reviewed the software for the modified StatStrip Glucose Hospital Meter with Wi-Fi option. The software development, validation &verification processes are acceptable.

3. Specimen Identification:

   The Nova StatStrip Glucose Hospital Meter memory will store 1000 patient tests, 200 QC tests, and 4000 operators.

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, QC 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:

   As established in k060345, the meter does not require the user to input a test strip code.

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 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 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:

The modified StatStrip Glucose Hospital Meter System with Wi-Fi option has been tested to meet the applicable requirements.

6) Wireless Data Transmission Test:

Six Nova StatStrip Glucose Hospital Meters with wireless option were used in a wireless data transmission functional testing at a representative hospital environment. A total of 654 results were transmitted from various locations in the hospital. Study protocols and acceptance criteria were reviewed and were found to be acceptable. The study results demonstrated that test results can be transmitted accurately and securely via the Wi-Fi function and that the device can coexist with other wireless devices in the intended environment.

7) Customer Care Service Center is available by calling 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.