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

I Background Information:

A 510(k) Number

K232075

B Applicant

Nova Biomedical Corporation

C Proprietary and Established Names

StatStrip Glucose Hospital Meter System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PZI	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

This submission is a Dual 510(k) and CLIA Waiver by Application (Dual Submission) tracked as K232075 and CW230017. This 510(k) is for modifications to a previously cleared device (K181043).

B Measurand:

Glucose in capillary finger stick whole blood, venous whole blood, arterial whole blood, neonatal arterial whole blood samples, and neonatal heel stick.

C Type of Test:

Quantitative amperometric assay, glucose oxidase

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(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 neonatal 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 neonatal 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.

The StatStrip Glucose Hospital Meter System includes the following components:
- StatStrip Glucose Hospital Meter
- StatStrip Glucose Test Strips

C Special Conditions for Use Statement(s):

- Rx - For Prescription Use Only
- For in vitro diagnostic use only
- Blood source - Use only whole blood. Do not use serum or plasma.
- 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 (4572 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 for arterial and venous specimens.
- It is not intended for screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.
- The system has not been evaluated for use with neonate venous blood.
- The system has not been evaluated with alternative site testing (AST).
- The system has not been evaluated for use in Tight Glycemic Control protocols as reported in the Greet Van den Berghe or NICE-SUGAR (Normoglycemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation) studies.
- Glucose results from alternative sampling sites should not be used to calibrate continuous glucose monitoring systems (CGMS) or entered into insulin dose calculators for dosage recommendations.
- Only auto-disabling, single use lancing devices may be used with this device
- Ranges for the StatStrip Glucose Hospital Meter using other commercially available glucose controls have not been established and may give erroneous results.

D Special Instrument Requirements:

StatStrip Glucose Hospital Meter

IV Device/System Characteristics:

A Device Description:

The StatStrip Glucose Hospital Meter System (previously cleared under K060345, K063821, K132121, K150281 and K181043) consists of a handheld StatStrip Glucose Hospital Meter with docking station and StatStrip Glucose Test Strips (sold separately). The Nova StatStrip Control Solutions (Levels 1, 2 and 3) and Nova StatStrip Linearity Test Kit solutions (5 levels) are also sold separately.

Modifications to the device include a change of the position of the test strip port, addition of wireless charging, changes to the user interface, increase in data storage capacity of operator records and the addition of a validated cleaning and disinfecting wipe.

B Principle of Operation:

The StatStrip Glucose 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 plasma equivalent result and is displayed on the meter.

C Instrument Description Information:

1. Instrument Name:

   StatStrip Glucose Hospital Meter

2. Specimen Identification:

   A built-in barcode scanner allows for scanning of the operator ID, patient ID and lot numbers. These fields can also be manually entered. The StatStrip Glucose Hospital Meter memory will store 1500 patient tests, 8000 operator records 200 QC test results.

3. 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. Data is transferred bi-directionally

between the meter, data docking station, and separate data management system each time a meter is placed into a data docking station.

4. Calibration:

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

5. Quality Control:

   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. Recommendations on when to test the control materials are provided in the labeling.

V Substantial Equivalence Information:

A Predicate Device Name(s):

StatStrip Glucose Hospital Meter System

B Predicate 510(k) Number(s):

K181043

C Comparison with Predicate(s):

Device & Predicate Device(s):	K232075	K181043
Device Trade Name	StatStrip Glucose Hospital Meter System	StatStrip Glucose Hospital Meter System
General Device Characteristic Similarities		
Intended Use/Indications For 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 throughout all hospital and all professional healthcare settings	Same

General Device Characteristic Differences		
Battery	Yes, 3.6V Li Polymer Battery (rechargeable) 2200 mAh	Yes, 3.7V Li Polymer Battery (rechargeable) 1250 mAh
Software Operating System (OS)	Linux	Windows CE
Data storage	1500 patient tests, 8000 operator records, 200 QC test results	1500 patient tests, 4000 operator records
Wireless Charging	Yes	No

VI Standards/Guidance Documents Referenced:

EN 60601-1-2:2014, Edition 4, Medical electrical equipment. Part 1-2: Collateral standard. Electromagnetic compatibility. Requirements and tests

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Precision was previously established in K060345. The sponsor conducted a supplementary precision assessment demonstrating that the precision of the device was not impacted by the modification.

2. Linearity:

   As established in K063821, the reportable range for the Nova StatStrip Glucose Hospital Meter System is 10 to 600 mg/dL.

3. Analytical Specificity/Interference:

   Potential interference from common endogenous and exogenous substances, as well as in vivo interference, was evaluated in K060345 and K132121.

4. Assay Reportable Range:

   As established in K063821, the reportable range for the Nova StatStrip Glucose Hospital Meter System is 10 to 600 mg/dL.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Traceability to NIST Standard SRM917B, as established in K060345.

   Test strip stability:
   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.

6. Detection Limit:

   This range was verified by the linearity established in K063821.

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   Not applicable.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Performance for capillary finger stick, venous whole blood and arterial whole blood samples from non-hospitalized patients was established in K060345.

   Performance for neonatal heel stick and neonatal arterial samples was established in K063821.

   Performance for venous and arterial, neonatal heel sticks and neonatal arterial samples from patients throughout the hospital was established in K132121.

   Performance for capillary whole blood samples for use in all hospitalized patients was established in K181043.

   The sponsor conducted a supplementary accuracy assessment demonstrating that the performance of the device was not impacted by the modification.

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

A usability study was conducted in which the changes to the device (e.g., relocation of the test strip port, use of a new bar code scanner, scroll functionality, etc.) were evaluated by CLIA waived users. The operators were given the meter, test strips, control solutions, user manual and the quick reference guide in order to perform the test. No other materials or instructions were provided, and the operators received no additional training to perform the test. Upon completion, each operator completed a questionnaire to evaluate the ease of using the candidate device. The participants were able to successfully perform the test, received accurate results, and found the StatStrip Glucose Hospital Meter System easy to use and the user manual and the quick reference guide easy to follow.

Supplemental bench accuracy studies were performed, in which the results from venous whole blood samples obtained from the StatStrip Glucose Hospital Meter were compared to the results from the comparator method (YSI 2300 STAT Glucose and L-Lactate analyzer) and were compared to results from matched samples on the predicate. The results were found to be acceptable to support the device modifications.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The following is included in the labeling:
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.

F Other Supportive Instrument Performance Characteristics Data:

Infection Control:
The device is intended for multiple-patient use. To support the changes to the exterior of the meter and the additional claimed cleaning and disinfecting wipe, the sponsor conducted cleaning and disinfection studies with the modified meter. Disinfection efficacy studies were performed on the external meter materials by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with each of the chosen disinfectants separately, Clorox Germicidal Wipes (EPA registration # 67619-12) and Super Sani Disposable Wipes (EPA registration #9480-4). A robustness study was also conducted by the sponsor that 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) using both of the wipes separately to simulate 3 years of multiple-patient device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

EMC:
The sponsor provided documentation certifying that acceptable electrical safety and electromagnetic compatibility (EMC) testing had been performed and the system was found to be compliant.

Software and Cybersecurity:
The sponsor provided documentation certifying that acceptable software validation and cybersecurity testing had been performed and the system was found to be compliant.

Battery life:
A battery consumption and battery life study was performed to assess the number of tests that can be run under normal operating conditions without recharging and demonstrated that the rechargeable battery will last as long as the meter life (minimum of 3 years).

Physical trauma to the meter:
A study was performed to confirm that there are no problems with the functionality of the StatStrip Glucose Hospital Meter following drop unit testing. The meter was dropped 10 times from a height of 60 inches such that each face of the item made impact with a hard surface (e.g. tile floor). All of the verification results were within the criteria limits and no deterioration in functionality was observed.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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