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

A. 510(k) Number:

k063821

B. Purpose for Submission:

Modification of current glucose monitoring device to expand the reportable range and to add neonate blood as a sample type

C. Measurand:

Whole Blood Glucose

D. Type of Test:

Quantitative, utilizing glucose oxidase technology

E. Applicant:

Nova Biomedical Corp.

F. Proprietary and Established Names:

Nova StatStrip Glucose Hospital Meter System

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345 Glucose test system
   21 CFR 862.1660 Quality control materials

2. Classification:

   Class II

3. Product code(s):

   CGA, JJX

4. Panel:

   75 (Chemistry)

H. Intended Use:

1. Intended use(s):

   See Indications for use below.

2. Indication(s) for use:

   The Nova StatStrip Glucose Hospital Meter is intended for *in vitro* diagnostic use by health care professionals and for Point-Of-Care usage for the quantitative measurement of glucose in capillary, venous, arterial, and neonate whole blood. It is indicated for use in a clinical setting by healthcare professionals as an aid to monitor the effectiveness of diabetes control.

   Nova StatStrip Glucose Test Strips are intended for use only with the StatStrip Glucose Hospital Meter for quantitative tests. The glucose meter is intended to quantitatively measure glucose (sugar) in whole blood. The Glucose Meter is calibrated to provide plasma equivalent results to laboratory methods. Nova StatStrip Glucose Test Strips are for testing outside the body (in vitro diagnostic use only).

   Nova StatStrip Control Solutions is intended for use with the Nova StatStrip Glucose Hospital Meter and Nova StatStrip Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results. There are three levels of controls, (Level 1, Level 2, and Level 3). These solutions will be offered for sale separately from the meter.

   Nova StatStrip Glucose Linearity Kit solutions are used to check the linearity of the Nova StatStrip Glucose Hospital Meter System. There are five levels of linearity solutions, (Level 1, Level 2, Level 3, Level 4, and Level 5).

3. Special conditions for use statement(s):

   Provides plasma equivalent results

   For professional use only

4. Special instrument requirements:

   Nova StatStrip Glucose Hospital Meter system

I. Device Description:

The Nova StatStrip Glucose Hospital Meter System contains the following:

1. StatStrip Meter
2. Charging Station
3. Vial of StatStrip Test Strips (25)
4. Battery (3.7 V Lithium)
5. Quick Reference Guide
6. Instructions for Use Manual
7. StatStrip Log book

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Nova StatStrip Glucose Hospital Meter

   Roche Accu-Chek Inform Meter

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

   k060345, k003846

3. Comparison with predicate:

Similarities and Differences

Characteristic	K063821 Modified Nova StatStrip Glucose Meter System	Predicate Nova StatStripGlucose Meter K060345	Predicate Roche Accu-Chek Inform Meter K003846
Measuring Range	10-600 mg/dL	20-600 mg/dL	10-600 mg/dL
Hematocrit Range	20-65 %	30-60 %	20-65 %
Operating Principle	No change from StatStrip predicate device	Electrochemical biosensor	Electrochemical biosensor
Intended Use (System)	The Nova StatStrip Glucose Hospital Meter is intended for *in vitro diagnostic use* by health care professionals and for Point-Of-Care usage for the quantitative measurement of glucose in capillary, venous, and arterial and neonate whole blood. It is indicated for use in a clinical setting by healthcare professionals as an aid to monitor the effectiveness of diabetes control	The Nova StatStrip Glucose Hospital Meter is intended for *in vitro diagnostic use* by health care professionals and for Point-Of-Care usage for the quantitative measurement of glucose in capillary, venous, and arterial whole blood. It is indicated for use in a clinical setting by healthcare professionals as an aid to monitor the effectiveness of diabetes control	The Accu-Check Inform Meter is designed to quantitatively measure the concentration of glucose in whole blood samples. The device is indicated for use health care professionals.

Sample type	No change from StatStrip predicate device	Whole blood	Whole blood
Sample size	No change from StatStrip predicate device	1.3 uL	4 uL
Sample application	No change from StatStrip predicate device	Test strip capillary draw	Test strip capillary draw
Handheld meter?	No change from StatStrip predicate device	YES	YES
Meter Calibration	No change from StatStrip predicate device	Automatic, no Calibration Code	Calibration code key needed
Data storage	No change from StatStrip predicate device	1200 QC and patient test results	4000 results
Test Time	No change from StatStrip predicate device	6 sec	26 sec
Weight	No change from StatStrip predicate device	8.8 oz.	12 oz
Bar code scanner	No change from StatStrip predicate device	YES	YES
Power source	No change from StatStrip predicate device	Rechargeable 3.7 V Lithium battery	Rechargeable 3.7 V Lithium battery
Accessories to the Meter:			
Charging station:	No change from StatStrip predicate device	Charging Station Base Unit	Charging Station Base Unit
Controls:	No change from StatStrip predicate device	Liquid, 3 levels	Liquid, 2 levels
Linearity Solutions	No change from StatStrip predicate device	5 levels	Liquid, 6 levels
Test Strips – Active reagent:	No change from StatStrip predicate device	Glucose Dehydrogenase and Glucose Oxidase	Glucose dehydrogenase

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

CLSI EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline, Second Edition 2004

CLSI EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline Evaluation of Matrix Effects; Approved Guideline, Second Edition 2003

CLSI EP9-A: Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline. Vol. 15, No. 17, 1995

CLSI EP17-A: Protocols for determination of limit detection and limit of quantitation; Approved Guideline.

EN ISO 15197: 2003, In Vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

L. Test Principle:

The Test Principle used by this device is electrochemical biosensor technology using Glucose Oxidase. The strip uses the enzyme Glucose Oxidase to produce an electrical current that will stimulate a chemical reaction. This reaction is measured by the Nova StatStrip Glucose Hospital Meter and displayed as a blood glucose result.

Glucose measurement is based on the following equations:

Glucose + Enzymes (oxidized form) → Gluconic acid + Enzymes (reduced form)

Enzymes (reduced form) + Ferricyanide → Enzymes (oxidized form) + Ferricyanide

Ferrocyanide $\xrightarrow[\text{Electrode}]{\text{-e-}}$ Ferricyanide

The current generated at the electrode is proportional to the glucose concentration of the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Precision studies were performed and established in k060345.

   Additional precision testing was performed on venous blood samples spiked with 4 target glucose concentrations between 5 and 60 mg/dL (6, 25, 40, 58 mg/dL) and 3 hematocrit levels (19%, 45%, 67%). Three lots of strips and 5 meters were used. Twenty measurements were taken for each lot of strips. The acceptance criteria are: for glucose level ≤ 50 mg/dL, ≤ 8% CV or <4.5 SD; and for glucose level from 51-150, ≤ 6% CV. All measurements met the sponsor's acceptance criteria.

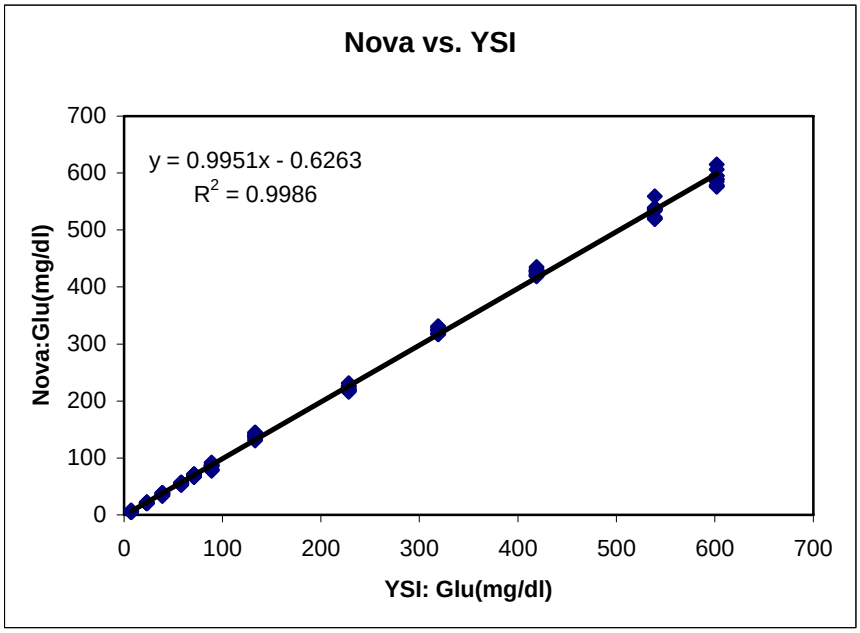
   b. Linearity/assay reportable range:

   Linearity studies were performed and established in k060345.

   Additional linearity studies were performed to verify the linearity range of 10 to 600 mg/dL. Samples were run in duplicate using 5 meters and one lot of test strips. Twelve glucose concentrations were prepared (spiked blood). Target glucose concentrations were at 5-10, 15-25, 30-40, 50-60, 65-75, 75-85, 130-150, 210-230, 300-340, 400-440, 500-550, and 560-600 mg/dL. The concentration range of 7 to 602 mg/dL was tested. The acceptance criteria are:

a correlation coefficient $r^2 \geq 0.95$, and the test strip performance will be acceptable if the measurement bias related to YSI (at all glucose levels) is within 15% or absolute error is ≤ 10.5 mg/dL., whichever one is greater.

The results of the Modified Nova glucose meter (candidate device) verses the YSI (reference method) results are plotted in the graph below.



All the measurements met the sponsor's acceptance criteria. The sponsor claims the linearity range is 10 to 600 mg/dL.

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

Please refer to k060345 for traceability and stability.

Controls were cleared in k060345.

d. *Detection limit:*

Detection limit studies were performed and established in k060345.

Limit of Blank (LoB) and Limit of Detection (LoD) studies were performed according to the CSLI EP17-A document. Blood bank samples were used and glucose concentrations tested using the YSI reference method. The LoD was determined by measuring 40 times of a low glucose sample on the modified Nova glucose meter and the YSI reference method. The sponsor chose the range of 10-600 mg/dL as the reportable range for the modified Nova glucose meter as determined in the linearity studies above.

e. *Analytical specificity:*

Analytical specificity studies were performed and established in k060345.

Hematocrit study: The sponsor performed the hematocrit study to verify that

varying hematocrit levels do not affect the glucose results reported by the candidate device at low glucose concentration levels.

Blood samples were prepared (spiked) with 8 target ranges of glucose at 5-15, 20-35, 40-55, 60-80, 100-150, 200-300, 350-450 and 550-650 mg/dL and at 4 hematocrit levels (18-25%, 40-46%, 48-55% and 63-68%). Samples were run in duplicate on 5 different meters and three different strip lots. The sponsor's acceptance criteria are:

1. Bias measurements related to YSI at all glucose levels must be within 15% or absolute error is < 10.5 mg/dL, whichever is greater.
2. In addition, the test strip performance will be acceptable if the results are within the following specifications:

Glucose level (mg/dL)	**CV %**
≤ 50	8% or SD = 4 mg/dL
51-150	≤ 6
151-400	≤ 4
401-600	≤ 4

All the measurements met the sponsor's criteria and the sponsor claims that the reportable hematocrit range is 20% to 65% for modified Nova glucose meter (candidate device).

f. Assay cut-off:

None applicable

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison was performed and established in k060345.

In addition, method comparison of arterial samples from 100 neonates and capillary samples from heel sticks of 100 neonates were performed from two different clinical sites.

i.) Arterial samples from discarded whole blood gas syringe samples from 100 neonates from a clinical site were used to evaluate the candidate device verses the predicate device (Accu-Chek Inform Meter, which was cleared for neonate use) and a reference method (YSI). In order to obtain sufficient patient specimens with glucose levels of less than 30 mg/dL, 26 neonatal arterial blood samples were allowed to glycolize. The glucose concentration range tested was 7 to 279 mg/dL and the hematocrit range was 26% to 59%.

The linear regression results of the candidate device and the predicate device as they compare with the YSI reference method are summarized in the table below:

Arterial blood comparison of methods

	Modified Nova glucose meter vs. YSI	**Roche Accu-Chek Inform meter vs. YSI**	**Roche Accu-Chek Inform meter vs. Nova glucose meter**
Correlation (r^2)	0.992	0.984	0.984
Slope	1.109	1.080	1.015
Intercept	-3.471	-6.945	4.842
N	200 (100 samples in duplicate)	200 (100 samples in duplicate)	200 (100 samples in duplicate)

The system accuracy results for glucose concentration based on the ISO 15197 document are as follows:

- For glucose values < 75mg/dL, 100% of the candidate's glucose results are within ± 15mg/dL compare to the YSI results.
- For glucose values > 75 mg/dL, 98% of the candidate's glucose results are within ± 20% of the YSI results.

ii.) Capillary blood samples from the heel sticks of 100 neonates from the NICU department of a children's hospital were used to evaluate the candidate device verses the J&J Vitros Chemistry analyzer (comparator method) and the predicate device (LifeScan SureStep Pro Meter, which was cleared for neonate use). 3 patient samples out of the 100 target samples were pooled together and spiked with a glucose solution in order to obtain glucose levels above 120 mg/dL. The age range of the patient tested was 1 to 25 days old, the hematocrit range was 29.7% to 66.9%, and the glucose concentration range tested was 25 to 411 mg/dL.

The linear regression results of the candidate device and the predicate device as they compare with the J&J comparator method are summarized in the table below:

Capillary blood comparison of methods

	Modified Nova glucose meter vs. J&J Vitros	SureStep Pro meter vs. J&J Vitros	Modified Nova glucose meter vs. SureStep Pro meter
Correlation (r^2)	0.986	0.996	0.981
Slope	0.986	1.041	0.942
Intercept	-3.425	-6.176	2.842
N	198 (99samples in duplicate)	100	198 (99 samples in duplicate)

The system accuracy results for glucose concentration based on the ISO 15197 document are as follows:

- For glucose values < 75mg/dL, 98% of the candidate's glucose results are within ± 15mg/dL compare to the J&J Vitros results.
- For glucose values > 75 mg/dL, 100% of the candidate's glucose results are within ± 20% of the J&J Vitros results.

Since the neonatal clinical samples did not cover the claimed meter range, results from a study of spiked samples with high glucose concentrations and varying hematocrits were provided by the sponsor to demonstrate acceptable performance **(**≤ 15% bias or absolute error is < 10.5 mg/dL from the YSI method). See the hematocrit study above.

b. Matrix comparison:

Established in k060345

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:

   The reference value for serum and plasma glucose for adult is 70-105 mg/dL and 60-100 mg/dL for a child*

   The Nova StatStrip Glucose Meter expected values were referenced from the literature:

   * Burtis, Carl A. and Ashwood, Edward R., ed. 1999. Tietz Textbook of Clinical Chemistry. Philadelphia, PA: W.B. Saunders Co.

   The sponsor states in the labeling that each laboratory should establish and maintain its own reference values. The values given above should be used only as a guide.

N. Instrument Name:

Nova StatStrip Glucose Hospital Meter

O. System Descriptions:

1. Modes of Operation:

   The Nova StatStrip Glucose Hospital Meter used with the Nova StatStrip Glucose Test Strips is a single use test system used to quantitatively measure blood glucose levels, also known as blood sugar, from fresh capillary (fingertip) whole blood, venous and arterial and neonate. The Nova StatStrip Glucose Test Strips are for *in vitro* diagnostic use only.

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, 500 QC Tests, and 4000 Operator ID's.

4. Specimen Sampling and Handling:

   Refer to k060345

5. Calibration:

   Refer to k060345

6. Quality Control:

   Refer to k060345

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

Refer to k060345

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.