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

A. 510(k) Number:

k060345

B. Purpose for Submission:

Premarket Notification 510(k) of intention to manufacture and market the Nova StatStrip Glucose Hospital Meter.

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

StatStrip Control Solutions

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.1345, Glucose test system.

   21 CFR §862.1660, Single (Specified) Analyte Controls (Assayed and Unassayed)

2. Classification:

   Class II (analyte)

   Class I, reserved (controls)

3. Product code:

   CGA (glucose)

   JJX (control)

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, 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.

   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.

3. Special conditions for use statement(s):

   Provides plasma equivalent results.

   For professional use only.

This device has not been evaluated for use in neonates.

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):

Lifescan Inc. SureStep Pro/Flexx Meter

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

k023194

3. Comparison with predicate:

Similarities and Differences		
Item	New Device Nova StatStrip Glucose Hospital Meter System k060345	Predicate Lifescan Inc. SureStep Pro/Flexx Meter k023194
Measuring Range	20 - 600 mg/dL	0-500 mg/dL
Operating Principle	Electrochemical biosensor	Reflectance photometry
Intended Use	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.	For in vitro diagnostic use for the quantitative measurement of glucose in venous, capillary, arterial and neonatal whole blood samples. Lay users at home can also use these systems.
Sample Type	Whole blood	Whole blood

Similarities and Differences		
Item	New Device Nova StatStrip Glucose Hospital Meter System k060345	Predicate Lifescan Inc. SureStep Pro/Flexx Meter k023194
Sample Size	1.3 µL	2-3 µL
Sample Application	Test strip capillary draw	Test strip capillary draw
Handheld Meter?	Yes	Yes
Meter Calibration	Automatic	Automatic
Data Storage	1500 QC and patient test results	1500 QC and patient test results
Test Time	6 seconds	30 seconds
Weight	8.8 ounces	12.5 ounces
Bar code scanner	Yes	Yes
Power source	Rechargeable 3.7 V Lithium battery	Three AA batteries
Accessories to the Meter:	Charging station	Module cradle or serial cable
Controls	Liquid, 3 levels	Liquid, 3 levels
Linearity Solutions	5 levels	5 levels
Test Strips – Active Reagent	Glucose Dehydrogenase and Glucose Oxidase	Glucose Oxidase

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

The manufacturer of the Nova StatStrip Glucose Hospital Meter certifies that its device complies with the following:

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

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

EP7-P CLSI: Interference Testing in Clinical Chemistry; Approved Guideline. Vol 6, No. 13, 1986

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

FDA Guidance Document Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005

EN60601-1-2 Electromagnetic Compatibility – Medical electrical equipment

EN61000-4-2 Electromagnetic Discharge

EN61000-4-3 Radiated Electromagnetic Fields

EN61000-4-8 Power frequency Magnetic Immunity Test

IEC 61000-4-3 Electromagnetic compatibility (EMC).

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 $\xrightarrow[\text{Electrode}]{-e^-}$ 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:

StatStrip Meter Day to Day Precision- Controls:

According to the sponsor precision studies were based on CLSI Document EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition. Three levels of controls were run over several days using two strip lots and two meters. The sponsor's acceptance criteria were the test strip performance will be acceptable if the results are within the following specifications:

Glucose Level (mg/dL)	CV %/SD
≤50	≤ 9% (or SD <4.5)
51- 150	≤ 7
151- 400	≤ 6
401-600	≤ 5

The summary of Day to Day Precision results are presented in the table below.

Lot No	1			2		
Sample (n)	80			80		
	mean	CV%	SD	mean	CV%	SD
Control Level 1	79.0	3.5	2.78	78.8	3.6	2.84
Control Level 2	202.0	4.4	8.83	205.6	4.7	9.75
Control Level 3	306.6	3.8	11.7	304.4	3.4	10.4

Within Run Precision:

According to the sponsor within run precision testing was performed on five levels of linearity solutions and four venous blood samples spiked with various concentrations of glucose. Sixty samples were run for each using two lots of test strips. The sponsor's acceptance criteria were the test strip performance will be acceptable if the results are within the following specifications:

Glucose Level (mg/dL)	CV %/SD
≤50	≤ 9 (or SD <4.5)
51- 150	≤ 6
151- 400	≤ 4
401-600	≤ 4

The summary of within run precision results are presented in the below tables.

Summary of Within-run precision - Blood results

Lot No	Glucose level 1 (n=60)			Glucose Level 2 (n=60)			Glucose Level 3 (n=60)			Glucose Level 4 (n=60)		
	Mean (mg/dL)	CV (%)	SD	Mean (mg/dL)	CV (%)	SD	Mean (mg/dL)	CV (%)	SD	Mean (mg/dl)	CV (%)	SD
1	39	3.6	1.4	130	2.8	3.5	316	2.4	7.6	571	2.9	16.7
2	39	3.6	1.4	131	3.0	3.9	318	2.1	6.5	573	1.9	11.2

Summary of Within-run precision – Linearity solutions result

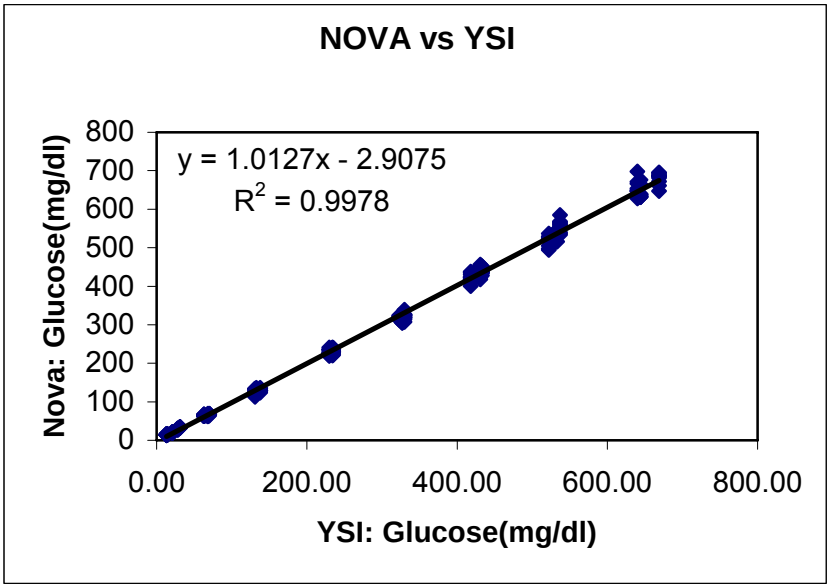
Lot #	Linearity level 1 N=60			Linearity Level 2 N=60			Linearity level 3 N=60			Linearity level 4 N=60			Linearity level 5 N=60		
	Mean (mg/dl)	CV%	SD	Mean (mg/dl)	CV%	SD	Mean (mg/dl)	CV%	SD	Mean (mg/dl)	CV%	SD	Mean (mg/dl)	CV%	S.D
1	29	5.0	1.5	74.5	2.3	1.7	201	3.3	6.6	301	1.9	5.7	595	1.7	10
2	29	4.7	1.4	75	2.1	1.5	200	2.5	5.0	300	2.4	7.1	593	1.5	9.1

b. Linearity/assay reportable range:

The sponsor indicated that the linearity studies protocol was developed according to CLSI Document EP6-A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline Evaluation of Matrix Effects; Approved Guideline – Second Edition. The Nova StatStrip Meter system was tested to verify linearity of the system using blood samples with glucose concentrations between 10-700 mg/dL. Venous blood samples were prepared by spiking blood with 9 different concentrations of glucose and 3 levels of hematocrit (30%, 44%, and 59%). Samples were run in duplicate on 5 meters for each level. A total of 30 samples were run for each glucose concentration.

The sponsor's acceptance criteria were a correlation coefficient $R^2 \geq 0.95$, and the test strip performance will be acceptable if the measurement bias relate to YSI (at all glucose levels) is within 15% or absolute error is less than 10.5 mg/dL, which ever one is greater. The measurement range tested was 20 – 600 mg/dL.

YSI 2300 VS StatStrip Hospital Meter



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

According to the sponsor, the linearity and control solutions are traceable to NIST Standard SRM917B. The sponsor's determined nominal glucose concentration for the Nova Linearity Solutions were:

Level 1:	30 mg/dL	
Level 2:	80 mg/dL	(same as Control solution Level 1)
Level 3	210 mg/dL	(same as Control Solution Level 2)
Level 4	320 mg/dL	(same as Control Solution Level 3)
Level 5	590 mg/dL	

Storage of Closed Vial

Stability studies were performed by the sponsor to verify performance of the Nova StatStrip and Controls after prolonged storage. Stability was assessed using accelerated and real time aging studies. The control solutions (Level 1, 2) were stored at 25, 40, and 50°C. The control solutions were tested at day1, 2 month, 3 month, and 4 month intervals. The predicted shelf life using results from the accelerated study was calculated using the Arrhenius equation (twice the amount of shelf life time for each 10 degree increase in temperature). According to the sponsor, results from solutions stored at 50 degrees C for four months predict stability at room temperature for 24 months.

The sponsor's acceptance criteria were all control values to be within acceptable range values for the control lot. The results described indicate that the control solutions are stable for 4 months at storage temperatures of 25°, 40° and 50°C. The stability of the control solutions are estimated to be 24 months at room temperature, with the actual real time stability study continuing through 25 months.

Shelf Life of Opened Vials

The sponsor performed open vial stability studies which included control solutions (Level 1 and 2) that were stored at RT and sampled over a 3 month period. Five meters were used and samples were run in duplicate. The sponsor's acceptance criteria were all results to be within the values specified as the control range. The results described support the stability of the control solutions up to 3 months after opening.

Shelf Life Test Strips

The sponsor performed shelf life stability studies on the Nova StatStrip Test strips that were stored at the recommended temperature (25°C) after 3 months of storage. Additional strips were also stored at 30 ^{o}C, 40 ^{o}C, and 50 ^{o}C for up to 3 months. Using the Arrhenius equation, the sponsor determined that strips stored at elevated temperatures for 3 months can be correlated to storage of strips at room temperature for 18 months. Real time storage studies are ongoing and will continue up to 20 months.

Two lots of strips were used in this study. Spiked blood samples at three concentrations of Glucose were used and results compared to the YSI 2300 Stat Plus analyzer. According to the sponsor the samples were run in triplicate on 5 meters at 3 target Glucose concentrations, and at each temperature at day 1, 1 month, and 3 months of storage. The sponsor's acceptance criteria were the change at any temperature is acceptable if the results are within the following specifications:

Glucose Level (mg/dL)	CV %	Bias
≤50	≤ 8 or +/- 4 mg/dL	+/- 10.5mg/dL
51- 150	≤ 6	+/- 15%
151- 400	≤ 4	+/- 15%
401-600	≤ 4	+/- 15%

Based on the sponsor's acceptance criteria the results of the stability studies indicate that the StatStrip test strips are stable at the recommended temperature for 18 months.

Open Vial Stability

The sponsor performed open vial stability of the Nova StatStrips. The StatStrips were stored up to 15 weeks at room temperature and tested each week. Two levels of controls were run after vial was opened for 2 minutes and then 10 minutes. The sponsor's acceptance criteria were all control results to be within range for that Lot. Based on the sponsor's acceptance criteria the results of this study indicate that the StatStrip test strips are stable up to 15 weeks after the vial has been opened when stored as indicated.

Shelf Life Linearity Solutions

The Linearity Solutions levels 2, 3 and 4 are the same as the formulations of Control solutions levels 1, 2, and 3 respectively. The stability studies for the remaining levels 1 and 5 are currently in progress. Studies to verify stability of solutions up to 24 months unopened and 3 months after opening will be completed prior to marketing these solutions.

d. Detection limit:

The limit of detection has been defined as a signal equivalent to three times the standard deviation of the noise level. To obtain an estimate of the limit of detection a whole blood sample glucose concentration was reduced by glycolysis over 40 hours. The whole blood sample was analyzed using forty replicate StatStrip measurements and compared to the reference YSI instrument.

The following tables summarize the mean, S.D. and CV from replicate StatStrip glucose measurements of a series of whole blood samples, compared to the YSI reference, at a hematorcrit of 30, 44, and 59 with glucose concentrations spanning the reportable glucose range of 20 mg/dL to 600 mg/dL:

Summary of Whole Blood Glucose at Hct 30

Mean StatStrip (mg/dL), n = 10	S.D.	CV	Reference YSI (mg/dL)
14.7	± 1.2	7.9%	13
33.4	± 0.8	2.5%	31
64.2	± 1.8	2.7%	63
129.5	± 4.4	3.4%	133

Mean StatStrip (mg/dL), n = 10	S.D.	CV	Reference YSI (mg/dL)
231.3	± 5.1	2.2%	235
318.6	± 3.8	1.2%	323
422.0	± 11.4	2.7%	418
517.5	± 13.9	2.7%	522
641.8	± 15.6	2.4%	644

Summary of Whole Blood Glucose at Hct 44

Mean StatStrip (mg/dL), n = 10	S.D.	CV	Reference YSI (mg/dL)
14.1	± 1.0	7.1%	13
29.0	± 1.3	4.6%	28
64.8	± 2.1	3.2%	68
130.1	± 3.7	2.8%	138
233.2	± 7.1	3.0%	234
316.4	± 7.4	2.3%	327
433.8	± 12.0	2.8%	431
536.9	± 9.2	1.7%	537
652.9	± 20.9	3.2%	640

Summary of Whole Blood Glucose at Hct 59

Mean StatStrip (mg/dL), n = 10	S.D.	CV	Reference YSI (mg/dL)
15.4	± 1.1	7.0%	14
20.1	± 1.0	4.9%	21
67.5	± 1.5	2.2%	70
125.4	± 6.9	5.5%	131
229.5	± 7.2	3.1%	230
321.9	± 8.6	2.7%	330
441.7	± 8.3	1.9%	433
555.8	± 16.1	2.9%	537
679.7	± 15.4	2.3%	669

e. Analytical specificity:

According to the sponsor data was analyzed for chemical interference according to the guidelines given by CLSI document EP7-P. Several compounds were studied to determine if their presence affected the reporting of glucose results in whole blood. One lot of strips and three levels blood glucose concentrations of 20-100, 320-400, and 650-750 mg/dL were used for the study. The sponsor's acceptance criteria were the test strip performance will be acceptable if the measurement accuracy relate to YSI (at all glucose levels of glucose and interference levels) is within 15% or absolute error is less than 10.5 mg/dL. The strip performance will be acceptable if the

coefficient of variation (CV%) is within the following specifications.
The sponsor's acceptance criteria were the accuracy relating to the YSI reference method must be within the following specifications:

Glucose Level (mg/dL)	CV %	Bias
≤50	≤ 8 or SD 4.5mg/dL	+/- 10.5mg/dL
51- 150	≤ 6	+/- 15%
151- 400	≤ 4	+/- 15%
401-600	≤ 4	+/- 15%

Based on the sponsor's acceptance criteria the compounds tested did not interfere with reporting glucose results up to the lowest and highest concentrations tested**.**

Potential Interference Substances Study Summary

Interference Studies	Interference Concentration (mg/dl)	GLU Conc. 20- 100 mg/dl n=24			Interference Concentration (mg/dl)	GLU Conc. 260-400 mg/dl n=24			Interference Concentration (mg/dl)	GLU Conc. 620-750 mg/dl n=24		
		CV %	% Bias	YSI		CV %	% Bias	YSI		CV %	% Bias	YSI
Acetaminophen	0	1.5	1.0	77	0	2.4	3.0	314	0	1.5	2.7	680
	10	1.6	14.9	77	10	1.1	1.7	311	10	1.9	3.2	682
Ascorbic Acid	0	2.3	6.7	86	0	2.1	4.5	298	0	1.4	1.0	690
	10	2.2	2.5	81	10	3.5	5.7	275	10	1.8	0.5	685
Bilirubin	0	2.2	2.1	72	0	2.2	2.0	308	0	1.1	1.5	691
	15	1.3	1.4	70	15	1.9	0.3	307	15	1.4	0.3	687
Cholesterol	0	2.8	3.2	85	0	1.8	1.6	378	0	1.2	0.9	691
	500	2	1.5	85	500	0.9	0.6	379	500	0.9	1.5	691
Creatinine	0	2.4	1.3	61	0	1.1	2.0	369	0	0.9	1.7	683
	6	1.8	3.0	56	6	1.2	1.8	367	6	1.4	3.0	679
Dopamine	0	3.1	0.5	60	0	1.7	0.4	339	0	3.4	4.0	719
	10	2.8	6.6	58	10	1.3	9.8	336	10	2	0.4	706
Ephedrine	0	2.5	0.6	54	0	1.7	1.5	375	0	1.4	1.4	653
	0.9	3.2	0.4	51	0.9	2.2	0.1	368	0.9	0.6	0.6	657
D(+) Galactose	0	3.8	2.1	61	0	1.2	2.2	332	0	2.2	2.2	682
	350	2.5	7.6	63	350	1.6	5.3	327	350	0.5	8.2	668
Ibuprofen	0	3.8	10.4	55	0	1.4	1.6	324	0	1.8	3.7	683
	48	3.2	6.1	54	48	0.9	0.5	325	48	1.3	2.3	676
L-dopa	0	2.9	3.9	51	0	1.4	1.6	364	1	1.5	2.3	700
	100	2.9	5.7	49	100	1.9	1.9	361	100	2.4	2.5	682
D(+) Maltose Monohydrate	0	3.7	1.9	79	0	1.6	1.2	337	0	0.9	2.6	637
	240	1.4	6.6	79	240	1.5	1.0	336	240	1	1.8	630
D(+) Maltotetraose	0	1.3	5.1	65	0	1.3	1.2	297	0	3.2	2.0	657
	240	3.1	1.6	63	240	1.9	2.2	296	240	0.7	6.4	644
D(+) Maltotetriose	0	3.2	1.0	72	0	2.4	2.2	335	0	2	1.5	716
	240	1.7	5.8	72	240	3.8	1.5	330	240	1.7	1.7	716

Interference Studies	Interference Concentration (mg/dl)	GLU Conc. 20- 100 mg/dl n=24			Interference Concentration (mg/dl)	GLU Conc. 260-400 mg/dl n=24			Interference Concentration (mg/dl)	GLU Conc. 620-750 mg/dl n=24		
		CV %	% Bias	YSI		CV %	% Bias	YSI		CV %	% Bias	YSI
Methyl dopa	0	1.9	4.2	48	0	1.4	5.3	376	0	1.6	3.5	685
	1	3.7	4.9	47	1	1.2	1.0	364	1	1.5	1.6	690
Salicylate	0	3.9	0.4	70	0	1	2.8	343	0	1.2	0.4	664
	30	3.1	3.0	66	30	0.7	4.7	343	30	2	0.0	657
Tetracycline	0	2.8	2.8	60	0	2.3	2.3	353	0	3.1	1.9	697
	30	3	0.4	53	30	5.6	5.6	357	30	1.8	5.9	692
Tolazamide	0	4.3	1.6	51	0	5.3	5.3	355	0	1.2	4.0	667
	15	4.5	0.6	50	15	4.2	4.2	344	15	2.1	0.4	660
Tolbutamide	0	2.6	4.8	56	0	3.2	0.1	361	0	2	1.9	711
	45	2.6	2.3	53	45	1.9	0.3	350	45	2.7	1.1	682
Triglycerides	0	4.7	2.0	87	0	2.4	1.9	391	0	2.6	0.0	705
	750	2.2	1.0	84	750	2.1	1.3	387	750	2.2	1.1	701
Uric Acid	0	3.1	3.9	57	0	2	2.0	358	0	1.3	3.4	663
	20	4.3	8.9	53	20	2.2	1.7	347	20	1.6	1.1	656

Hematocrit Study

The sponsor performed studies to verify that varying hematocrit levels do not affect the glucose results reported by the Nova StatStrip Meter. This study was performed as part of the Within-Day Precision Study. Blood samples were prepared with four target ranges of Glucose at 30-80, 120-200, 300-400, and 500-650 mg/dL and at three hematocrit levels (28-33%, 42-48% and 55-62%). Twenty replicates of each were run on two strip lots.

The sponsor's acceptance criteria were the test strip performance will be acceptable if the results are within the following specifications.

Glucose Level (mg/dL)	CV %/SD
≤50	≤ 9 (or SD <4.5)
51- 150	≤ 6
151- 400	≤ 4
401-600	≤ 4

Based on the sponsor's acceptance criteria the results show that hematocrit does not affect the reporting of glucose levels from 30% to 60% hematocrit.

		Glucose Level 1 (20 Measurements)			Glucose Level 2 (20 Measurements)			Glucose Level 3 (20 Measurements)			Glucose Level 4 (20 Measurements)		
Lot No.	**Hct %**	**Mean mg/dL**	**CV %**	**SD**	**Mean mg/dl**	**CV%**	**SD**	**Mean mg/dL**	**CV%**	**SD**	**Mean mg/dL**	**CV %**	**SD**
1	**30**	43	3.4	1.5	127	4.2	5.3	318	2.9	9.1	509	2.6	13.3
	45	39	3.6	1.4	130	2.8	3.5	316	2.4	7.6	571	2.9	16.7
	60	30	9.6	2.9	122	4.0	4.9	327	3.0	9.9	576	3.0	17.4
2	**30**	45	3.1	1.4	128	3.5	4.5	316	2.9	9.1	519	3.0	15.4
	45	39	3.6	1.4	131	3.0	3.9	318	2.1	6.5	573	1.9	11.2
	60	30	6.1	1.8	130	3.7	4.8	328	1.6	5.2	571	2.7	15.3

Environmental Testing

To study the affect of Altitude/Oxygen on the Nova StatStrip Hospital Meter System the sponsor spiked whole blood samples with three concentration levels of glucose (target ranges 20-100, 200-300, and 500-600mg/dL) and at 3 hematocrit levels (30%, 44%, and 59%). Samples were tested in duplicate on three meters, at three simulated altitude conditions (approximate): 33mmHg, 94 mmHg, and 226mmHg O_2. (total number of samples at each Glucose concentration at each oxygen partial pressure was n=18). These same samples were also tested by the reference method (YSI 2300 Stat Plus Analyzer).

The normal partial pressure of oxygen (PO_2) in capillary blood is about 100 mmHg at sea level. At the altitude of 15,000 ft the corresponding partial pressure of oxygen in capillary blood is about 32 mmHg. See the table below.

Corresponding Altitude with PO_2 in Blood

Altitude (ft)	**Atmospheric Pressure (mmHg)**	**PO_2 in Blood (mmHg)**
0	760	102
5000	632	75
15000	429	32

The sponsor's acceptance criteria were the system performance will be acceptable if the results are within the following specifications.

Glucose Level (mg/dL)	CV %	Bias
≤50	≤ 8 or +/- 4mg/dL	+/- 10.5 mg/dL
51- 150	≤ 6	+/- 15%
151- 400	≤ 4	+/- 15%
401-600	≤ 4	+/- 15%

Based on the sponsor's acceptance criteria the results of the Glucose Meter show no affect of altitude on accurately determining the glucose concentration.

Summary of Altitude/Oxygen Effect

Oxygen tension 32±4mmHg (Equivalent to Capillary blood @ 15,000 ft)				Oxygen tension 95±6mmHg (Equivalent to Capillary Blood @ sea level)				Oxygen tension 225±10mmHg (Equivalent to Arterial Blood on O_2 Therapy)			
(n=18)				(n=18)				(n=18			
Mean (mg/dL)	YSI	Bias (%)	CV (%)	Mean (mg/dL)	YSI	Bias (%)	CV (%)	Mean (mg/dL)	YSI	Bias (%)	CV (%)
92.9	94	1.2	4.3	93.6	93	0.6	4.5	92.0	93	1.1	3.5
230.8	235	1.8	4.0	227.0	230	1.3	4.0	228.5	234	2.4	3.9
552.1	535	3.2	1.7	539.1	530	1.7	2.4	544.9	535	1.9	1.8

f. Assay cut-off:

Not Applicable for this type of device.

2. Comparison studies:

a. Method comparison with predicate device:

Nova Biomedical sponsored a single center, comparison study at a University Medical Center to evaluate the performance of the proposed Nova StatStrip Meter compared to the predicate device (Sure Step Pro/Flexx Meter) and the (YSI) Reference Method. Three sites within the Medical Center where Point of Care Glucose testing is regularly performed were the Diabetes Clinic, Emergency Department, and Inpatient Nursing Unit. There were 120 patients enrolled in this study, 40 from each respective site.

Results were reported as correlation between each of the three methods for venous blood, and between the Sure Step Pro/Flexx and the proposed Nova StatStrip Hospital Meter for the capillary draws. In addition to patient samples, control solutions (Level 1, 2, 3) were run. According to the sponsor the study was designed according to CLSI document EP9-A, Method Comparison and Bias Estimation Using Patient Samples; Approved Guidelines.

Venous Blood Samples

The samples were drawn from a venous catheter into a heparinized syringe in 500 µl increments for each subject. From the syringe 150 µl was taken for the YSI analyzer and1 µl for the Nova StatStrip Meter. The linear regression results are summarized below.

Venous Blood Comparison of Methods

	Nova StatStrip Meter VS YSI
Correlation (r^2)	0.9858
Slope	0.991
Intercept	-2.22
N	120

According to the sponsor, the individual percent error is the difference between the YSI glucose result and the test meter result. The overall mean percent error (MPE) is the average of the individual percent error for all the results in the evaluation. The sponsor's acceptance criteria for accuracy were the MPE must be ≤ 15% to pass the necessary accuracy requirement. The accuracy results for the Nova Biomedical proposed meter are summarized in the below table.

Hospital Site	**MPE Test Meter Nova Biomedical Stat Strip**	**N**
Diabetes Clinic	2.00%	40
Emergency Department	1.92%	40
Inpatient Nursing Unit	3.36%	40
OVERALL	2.42%	120

Linear Association

The sponsor's linear association or correlation between the blood glucose results from the Nova Biomedical proposed meter and predicate meter was performed by calculation of the Correlation Coefficient and by Simple Linear Regression analysis. The table below shows the correlation between meters for each site and overall.

Correlation Results

Hospital Site	**Test Meter Nova Biomedical StatStrip**	**Predicate Meter Lifescan Sure Step Pro**
Diabetes Clinic	0.9979	0.9969
Emergency Department	0.9809	0.9902
Inpatient Nursing Unit	0.9786	0.9853
OVERALL	0.9929	0.9931

Capillary whole blood Samples

The sponsor indicated that at the same time venous samples were being drawn, capillary blood was drawn through a finger stick. Blood from the finger stick was placed on the Nova StatStrip Hospital Meter test strip and the Sure Step Pro/Flexx test strip for analysis. The table below summarizes the results of a linear regression analysis for this comparison.

Capillary Blood Sure Step Pro/Flexx vs. Nova StatStrip Hospital Meter

Comparison of Methods

Correlation (r^2)	0.9601
Slope	1.0042
Intercept	-4.161
N	89

Arterial Blood

The sponsor performed a separate study to test glucose concentrations in Arterial Blood with the proposed Nova StatStrip Glucose Meter and a reference method (YSI). Nova obtained 129 blood sample retains from Boston Medical. No patient identifier information was provided with the samples. All arterial blood samples that had a glucose concentration above 250 mg/dL were spiked with glucose to obtain higher values. Samples were run in duplicate on both the Nova StatStrip Meter and the YSI reference method. The results of the linear regression analysis for this comparison are presented below.

Arterial Blood YSI versus Nova StatStrip Meter

Comparison of Methods

Correlation (r^2)	0.9968
Slope	1.01
Intercept	-4.61
N	129

b. Matrix comparison:

The accuracy of the Nova StatStrip Glucose Meter was accessed by comparing the glucose results obtained from the Nova StatStrip with the results obtained from the YSI 2300 Stat Plus Analyzer (Yellow Springs Instrument Co., Yellow Springs, OH) for venous and arterial specimens and the Sure Step Flexx Blood Glucose Meter

(Lifescan Inc., Milpitas, CA) for capillary specimens. Capillary and venous specimens were obtained and tested at 3 sites within one hospital. Arterial samples were obtained from a secondary hospital and tested on the Nova StatStrip Glucose Meter. Please see the above capillary, venous and whole blood method comparisons.

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):

4. Clinical cut-off**:**

   Not Applicable

5. Expected values/Reference range:

   The Normal adult fasting blood glucose range for a person is 70-110 mg/dL.*

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

   * Burtis, Carl A. and Ashwood, Edward R., ed 1998 Carbohydrates (Sachs, DB): Tietz Textbook of Clinical Chemistry. Philadelphia, PA: W.B. Saunders Co.

   High Glucose Values: - If the test result is higher than 600 mg/dL, the Glucose Meter will read **"HI"**. Retest using a new test strip.

   Low Glucose Values: - If the test result is lower than 20 mg/dL, the Glucose Meter will read **"LO"** Retest using a new test strip.

   If a **HI** or **LO** reading is obtained, users are instructed to run a control test.

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 samples. The Nova StatStrip Glucose Test Strips are for in vitro diagnostic use only. The Nova StatStrip Glucose Hospital Meter is not intended for use with neonates.

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:

   Testing on Fingertips – Refer to the Nova StatStrip Glucose Meter Instructions for Use Manual for detailed meter information prior to testing. Items needed: StatStrip Glucose Meter, lancet, and Nova StatSrtip Gluose Test Strips.

   1. From the Patient Test ID screen, press the Accept soft key
   2. The Enter Patient ID screen displays. Enter the patient's ID
   3. Once the Patient's ID has been entered, press the Accept soft key
   4. The enter Strip Lot screen displays. Enter or scan the strip lot number
   5. Once the Lot Number has been added, press the Accept soft key
   6. The Insert Strip screen displays. Insert a test strip as shown on the meter screen
   7. Wash patient's hand with water then dry thoroughly. Alternatively, use alcohol pads to clean area; dry thoroughly after cleaning.
   8. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow
   9. Use a lancet to puncture the finger
   10. Squeeze the finger to form a drop of blood
   11. The Apply Sample screen should be displaying. When the blood drop appears, touch the end of the test strip to the blood drop until the well of the test strip is full and the meter beeps. Meter displays the Apply Sample screen
   12. The test results will appear in 6 seconds (NOTE: do not remove the test strip while the countdown n sin progress)
   13. To accept the result, press the Accept soft key. To reject the result, press the Reject soft key. To add a comment, press the Comment soft key (See StatStrip

Glucose Meter IFU Manual, Section 2.4 Add Comment to Result). All results (Accepted/ Rejected) are stored in the memory of the meter.

14. The test strip can be removed and another test can be run.

5. Calibration:

Lot Specific adjusted calibration with pre-set test strip code number.

6. Quality Control:

Run Control Solution Test:

Nova StatStrip Glucose Control Solutions are used as a quality control check to make sure that the Nova StatStrip Glucose Meter and the Nova StatStrip Glucose Test Strips are working correctly. Each StatStrip Glucose Control Solution is intended for use only with the Nova StatStrip Glucose Stat Strips. A control solution test is performed the same way that a blood glucose test is performed except control solution is used in place of a blood drop. The control solution test confirms that the meter and test strips are working correctly. The control solution test results should fall within the range of results printed on the vial label of the control.

Each Nova StatStrip Glucose Control Solution should produce results that fall within the range of results printed on the vial label of the control being used. If the control solution test result is outside the range (is either higher or lower), the StatStrip Glucose Meter and test strip may not be working as a system.

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

The sponsor indicated that there are factors that may cause results to differ by more than 20% in some situations. These factors are listed below:

- Blood source – Use only whole blood. Do not use serum or plasma.
- Do not use the StatStrip Test Strips for testing neonates.
- Venous and capillary blood may differ in glucose concentrations by as much as 70 mg/dL, depending on the time of blood collection after food intake.
- Temperature and humidity extremes – Test results are best obtained when Nova StatStrip is used within and operating relative humidity of 10-90% (non-condensing). Testing outside these ranges may cause inaccurate results.
- Altitude – There is no effect of altitude up to 15,000 feet (4500 meters) above sea level.
- Venous Specimens – Fluoride (gray to tubes) or EDTA (purple top tubes) should not be used as preservatives for venous specimens.

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.