

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

A. 510(k) Number:

k132121

B. Purpose for Submission:

Modified device to expand the indications for use of venous and arterial blood samples for use in all hospitalized patients.

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 consists of a the 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.

Each Nova StatStrip Glucose Test Strip contains glucose oxidase (*Aspergillus sp.*) >1.0 IU, mediator >20 µg, and other nonreactive substances.

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):
k063821
3. Comparison with predicate:

Similarities and Differences		
Item	Predicate (k063821)	Candidate Device
Brand Name	Nova StatStrip Glucose Hospital Meter System	Nova StatStrip Glucose Hospital Meter System
Indications for Use/Intended Use	For the quantitative measurement of glucose in capillary, venous, arterial, and neonate whole blood as an aid in monitoring the effectiveness of glucose control.	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.
Enzyme	Glucose Oxidase	Same
Test Principle	Coulometric electro-	Same

Similarities and Differences		
Item	Predicate (k063821)	Candidate Device
	chemical sensor	
Sample type	Capillary finger stick, venous and arterial whole blood, and neonatal arterial and heelstick	Capillary finger stick, venous and arterial whole blood, neonatal arterial and heelstick. Venous, arterial, neonatal arterial, and heelstick in all hospitalized patients
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

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

- IEC 61010-1:2001; Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements.
- IEC 61010-2-101:2002; Safety Requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for In Vitro Diagnostic (IVD) Medical Equipment.
- EN55011: Industrial, scientific and medical equipment - Radio frequency disturbance characteristics - Limits and Methods of Measurement

L. Test Principle:

The Nova StatStrip Hospital Meter System is based on electrochemical biosensor technology and the principle of capillary action. The system quantitatively measure 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 the expansion of the indications for use to add the use of venous and arterial blood samples (lithium heparin) in hospitalized patients. The expanded indications for use is supported by a clinical study (see section M below). The meter, test strips, and software were not modified from the predicate.

1. Analytical performance:

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 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.

c. *Detection limit:*
The reportable range for the Nova StatStrip Blood Glucose Hospital Meter is 10 to 600 mg/dL. This range was verified by the linearity established in k063821; section M.1.b.

d. *Analytical specificity:*
Potential interference from some common endogenous and exogenous substances was established in k060345.

Additional interference testing was performed to support the additional intended use claims. To study the effects of commonly used drugs and endogenous substances on the StatStrip Glucose Hospital Meter System, one lot of strips and three levels of blood glucose concentrations (20 - 80 mg/dL, 100 - 200 mg/dL, and 250-400 mg/dL) were used. Blood samples at each glucose concentration were spiked with a toxic concentration of one of each of 80 potential interferents and tested on five Nova StatStrip Glucose Hospital Meters. The results were compared to results from unspiked, control samples and the concentrations at which no significant interference was observed are listed in the table below:

Potential Interfering Substance	Concentration at which no significant interference is observed (mg/dL)	Potential Interfering Substance	Concentration at which no significant interference is observed (mg/dL)
Acetaminophen	20 mg/dL	Lactose	500 mg/dL
Acetoacetate	51.0 mg/dL	L-dopa	5 mg/dL
Acetone	69.7 mg/dL	Lansoprizole	20 mg/dL

Potential Interfering Substance	Concentration at which no significant interference is observed (mg/dL)	Potential Interfering Substance	Concentration at which no significant interference is observed (mg/dL)
Acyclovir	0.6 mg/dL	Levofloxacin	1.8 mg/dL
Albuterol	0.06 mg/dL	Lidocaine	0.7 mg/dL
Amitriptyline	0.06 mg/dL	Lisinopril	0.5 mg/dL
Amoxicillin	5 mg/dL	Maltose	500 mg/dL
Ampicillin	0.8 mg/dL	Mannitol	6000 mg/dL
Atropine	0.01 mg/dL	Mannose	500 mg/dL
Ascorbic acid	22.5 mg/dL	Methyl-dopa	0.9 mg/dL
Beta-hydroxybutyrate	166.6 mg/dL	Metoprolol tartrate salt	1.8 mg/dL
Bilirubin	297.3 mg/dL	N-acetylcysteine	81.6 mg/dL
Captopril	0.6 mg/dL	Naproxen	40 mg/dL
Carbamazepine	1 mg/dL	Nifedipine	0.02 mg/dL
Cefaclor	35 mg/dL	Nortriptyline hydrochloride	0.02 mg/dL
Cholesterol	1000 mg/dL	Norepinephrine	10 mg/dL
Cimetidine	5 mg/dL	Olanzapine	0.2 mg/dL
Citric acid	384.3 mg/dL	Pancuronium bromide	0.4 mg/dL
Creatinine	5 mg/dL	Penicillin	72 mg/dL
Digoxin	0.3 µg/dL	Phenytoin	2.5 mg/dL
Diltiazem hydrochloride	0.1 mg/dL	Prednisone	1 mg/dL
Dopamine	20 mg/dL	Propofol	3.2 mg/dL
Enalapril	0.5 mg/dL	Propranolol hydrochloride	0.3 mg/dL
Ephedrine	1 mg/dL	Ranitidine hydrochloride	1 mg/dL
Erythromycin	1.5 mg/dL	Salicylate	120 mg/dL
Ethanol	399.9 mg/dL	Sodium chloride	23.8 mg/dL
Famotidine	0.042 mg/dL	Sodium nitroprusside dehydrate	0.05 mg/dL
Fluconazole	2 mg/dL	Sorbitol	500 mg/dL
Fluoxetine hydrochloride	2 mg/dL	Sucrose	500 mg/dL
Fructose	500 mg/dL	Sulfamethoxazole	1.5 mg/dL
Furosemide	3 mg/dL	Tetracycline	30 mg/dL
Galactose	500 mg/dL	Theophylline	2 mg/dL
Galactose-1-	500 mg/dL	Tolazamide	45 mg/dL

Potential Interfering Substance	Concentration at which no significant interference is observed (mg/dL)	Potential Interfering Substance	Concentration at which no significant interference is observed (mg/dL)
phosphate			
Gentamicin sulfate	12 mg/dL	Tolbutamide	50 mg/dL
Glycerol	500 mg/dL	Triglyceride	1500 mg/dL
Heparin	1.2 mg/dL	Uric acid	23.5 mg/dL
Hydrochlorothiazide	2 mg/dL	Vancomycin hydrochloride hydrate	3 mg/dL
Hydrocortisone	20 mg/dL	Verapamil hydrochloride	0.1 mg/dL
Ibuprofen	20 mg/dL	Warfarin	1.2 mg/dL
Ketoprofen	6 mg/dL	Xylose	500 mg/dL

The sponsor also evaluated in vivo interference during the clinical performance evaluation in the new intended use population. See Clinical Studies (section M.3.c) below.

e. Assay cut-off:
Not Applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Performance for capillary finger stick samples was established in k060345.
Performance for neonatal heelsticks and neonatal arterial samples was established in k063821.

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):

The performance of the Nova StatStrip Glucose Hospital Meter System in hospitalized patients was established in this submission using venous (lithium

heparin) and arterial samples (lithium heparin) obtained from 1698 patients at 5 different hospitals.

The study was comprised of patients throughout the hospital which included emergency rooms, operating rooms, oncology departments, intensive care units, medical intensive care units, surgical intensive care units, cardiovascular surgical intensive care units, pediatric intensive care units, transplant departments, cardiac departments, nursing, and surgical departments.

Samples from patients, ages 1 month – 94 years of age, were analyzed using 4 test strip lots at each study site. Results obtained by a point of care user on the StatStrip Glucose Hospital Meter were compared to results obtained on the comparator method (Roche COBAS Modular P800 Chemistry System at sites 1, 2, 4 and 5, and the Beckman Coulter Synchron UniCel DxC 800 at site 3). Glucose results, patient conditions (see Patient Conditions table below for details), physiological status (e.g., pH, pO₂, pCO₂, sO₂, albumin, protein, red blood cell count, hematocrit, hemoglobin, platelets, white blood cell count, mean corpuscular volume (MCV), mean corpuscular hemoglobin concentration (MCHC), major histocompatibility complex (MHC), sodium, potassium, calcium, lactate, chloride, creatinine, blood urea nitrogen (BUN), triglycerides, Multiple Organ Dysfunction (MOD) score), and medication information (see the Medications table below for details) were collected during the study. The glucose ranges, according to the reference method, and the number of samples obtained at each study site are summarized in the table below:

Site	Specimen type	Glucose Range (mg/dL)	Number of Samples
1	Arterial	16-571	620
	Venous	22-600	132
2	Arterial	16-550	307
	Venous	20-582	186
3	Arterial	63-223	123
	Venous	0	0
4	Arterial	34-526	374
	Venous	0	0
5	Arterial	80-428	44
	Venous	90-362	29
Combined Sites	Arterial	16-571	1,468
	Venous	20-600	347

The results of the StatStrip Hospital Meter compared with the comparator method can be found in the tables below for each specimen type (arterial and venous) and at each of the study sites:

Arterial Specimens:

Analytical and System Accuracy Comparison: Glucose concentrations < 75 mg/dL

Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL	Exceeds ± 15 mg/dL
1	64/82 (78.0%)	75/82 (91.5%)	78/82 (95.1%)	79/82 (96.3%)	3/82 (3.7%)
2	79/93 (84.9%)	89/93 (95.7%)	91/93 (97.9%)	92/93 (98.9%)	1/93 (1.1%)
3	1/1 (100%)	1/1 (100%)	1/1 (100%)	1/1 (100%)	0/1 (0.0%)
4	19/25 (76.0%)	24/25 (96.0%)	25/25 (100%)	25/25 (100%)	0/25 (0.0%)
5	0/0 (Not Applicable)	0/0 (Not Applicable)	0/0 (Not Applicable)	0/0 (Not Applicable)	0/0 (Not Applicable)
All sites combined	163/201 (81.1%)	189/201 (94.0%)	195/201 (97.0%)	197/201 (98.0%)	4/201 (2.0%)

Analytical and System Accuracy Comparison: Glucose concentrations ≥75 mg/dL

Site	Within ± 5 %	Within ± 10 %	Within ± 12.5 %	Within ± 15 %	Within ± 20 %	Exceeds ± 20 %
1	362/538 (67.3%)	497/538 (92.4%)	515/538 (95.7%)	523/538 (97.2%)	532/538 (98.9%)	6/538 (1.1%)
2	120/214 (56.1%)	195/214 (91.1%)	208/214 (97.2%)	214/214 (100%)	214/214 (100%)	0/214 (0.0%)
3	83/122 (68.0%)	112/122 (91.8%)	115/122 (94.3%)	117/122 (95.9%)	120/122 (98.4%)	2/122 (1.6%)
4	257/349 (73.6%)	330/349 (94.6%)	340/349 (97.4%)	346/349 (99.1%)	348/349 (99.7%)	1/349 (0.3%)
5	22/44 (50.0%)	41/44 (93.2%)	42/44 (95.5%)	44/44 (100%)	44/44 (100%)	0/44 (0.0%)
All sites combined	844/1267 (66.6%)	1175/1267 (92.7%)	1220/1267 (96.3%)	1244/1267 (98.2%)	1258/1267 (99.3%)	9/1267 (0.7%)

Venous Specimens:

Analytical and System Accuracy Comparison: Glucose concentrations < 75 mg/dL

Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 12 mg/dL	Within ± 15 mg/dL	Exceeds ± 15 mg/dL
1	17/20 (85.0%)	20/20 (100%)	20/20 (100%)	20/20 (100%)	0/20 (0.0%)

2	51/59 (86.4%)	51/59 (96.6%)	58/59 (98.3%)	59/59 (100%)	0/59 (0.0%)
5	0/0 (Not Applicable)	0/0 (Not Applicable)	0/0 (Not Applicable)	0/0 (Not Applicable)	0/0 (Not Applicable)
All sites combined	68/79 (86.1%)	77/79 (97.5%)	78/79 (98.7%)	79/79 (100%)	0/79 (0.0%)

Analytical and System Accuracy Comparison: Glucose concentrations \geq 75 mg/dL

Site	Within \pm 5 %	Within \pm 10 %	Within \pm 12.5 %	Within \pm 15 %	Within \pm 20 %	Exceeds \pm 20 %
1	77/112 (68.8%)	108/112 (96.4%)	111/112 (99.1%)	111/112 (99.1%)	112/112 (100%)	0/112 (0.0%)
2	84/127 (66.1%)	116/127 (91.3%)	123/127 (96.9%)	127/127 (100%)	127/127 (100%)	0/127 (0.0%)
5	10/29 (34.5%)	22/29 (75.9%)	26/29 (89.7%)	29/29 (100%)	29/29 (100%)	0/29 (0.0%)
All sites combined	171/268 (63.8%)	246/268 (91.8%)	260/268 (97.0%)	267/268 (99.6%)	268/268 (100%)	0/268 (0.0%)

The following table includes the patient condition, StatStrip Glucose Hospital Meter result, comparator result and bias (mg/dL and %) for the 13 arterial results that exceeded \pm 15 mg/dL ($<$ 75 mg/dL glucose) or \pm 20% (\geq 75 mg/dL glucose) of the comparator method:

Sample type	Patient condition	Comparator Result (mg/dL)	StatStrip Result (mg/dL)	mg/dL bias	% bias
Arterial	Pneumonia	72	52	-20	-27.5
Arterial	COPD Exacerbation	58	83	25	42.2
Arterial	Sepsis	50	31	-19	-39.3
Arterial	Cardio Thoracic	59	96	37	39.5
Arterial	Cardio Thoracic	112	139	27	24.2
Arterial	Cardio Thoracic	83	130	47	56.5
Arterial	Cardio Thoracic	83	130	47	56.6
Arterial	Pre-Op Coronary Arterial Angiography	88	106	18	20.4
Arterial	Cardio Thoracic	132	101	-31	-23.3
Arterial	Pacemaker Surgical Implant	141	106	-35	-24.4
Arterial	Cardio Thoracic	135	94	-41	-30.7
Arterial	Post Thoracic Surgery	90	67	-23	-26.0
Arterial	27% Total Body Surface Area burns	122	122	-41	-34.0

Patient Conditions:

The study participants fell in to the following medical condition categories (bolded in left hand column) that included over 250 medical condition subclasses describing the reason for hospitalization. The number of patients that fell into each of the subclasses can be found in the table below:

Medical Condition Category	Medical Condition Sub-category/ Reason for Hospitalization	# of Patients
Burn Trauma	Burns	6
Cardiac	Observation: Thoracic Surgery	3
	Post thoracic surgery	141
	Pre-Operative Coronary Arterial Angiography	7
	Acute coronary syndrome	1
	Heart failure	14
	Acute Myocardial Infarction	46
	Ventricular Rhythm Disorders	9
	Arterial Vascular Disease	3
	Artery Disease	3
	Bradycardia	2
	Cardiac arrest	5
	Cardiogenic shock	2
	Cardiomyopathy	1
	Chronic heart failure	1
	Coronary Angiography	4
	Endocarditis	6
	Cardiac Gangrene	1
	Hypertension	2
	Myocardial Infarction/Ventricular-Fib	1
	Resuscitation	21
	Stable Angina	11
	Transient Ischemic Attack	1
	Angiography	1
	Endarterectomy	5
	Cardio Thoracic (Aortic Bypass Surgery)	12
	Cardio Thoracic (Aortic Rupture)	4
	Endarterectomy	7
	Femoral aneurism rupture	2
	Fibrosing mediastinitis	1
	Obstructive arteriopathy	1
	Pacemaker Surgical Implant	47
	Percutaneous Transluminal Ablation (PCTA Stent)	3
	Pericardial Surgery (Pericardial Patch)	1
	Aortic Aneurism	12
	Thoracic Surgery (Robotic Assisted)	1

Medical Condition Category	Medical Condition Sub-category/ Reason for Hospitalization	# of Patients
	Ventricular Septal Rupture	7
	Aortic stenosis	4
	Aortic valve replacement	17
	Cardio Thoracic (Arterial Valve Replacement (↑Aorta))	11
	Cardio Thoracic (Atrial Fibrillation (Maze + MVP))	8
	Cardio Thoracic (aortic valve replacement (AVR) + mitral valve replacement (MVR))	7
	Mitral Valve Replacement	34
	Cardio Thoracic (AVR + Mitral Valve Plasty(MPL))	3
	Coronary artery bypass graft (CABG) surgery	29
	Cardio Thoracic (CABG (1 art) + AVR)	9
	Cardio Thoracic (CABG (2 art) + AVR)	16
	Cardio Thoracic (CABG + AVR + Maze)	4
	Cardio Thoracic (CABG + MPL+ Maze)	9
	Cardio Thoracic (CABG > = 3 art. grafts (incl ven gr)	46
	Cardio Thoracic (CABG banned venous grafts)	7
	Cardio Thoracic (CABG robot Inc. ven 3art. > = graft)	4
	Cardio Thoracic (CABG robot vene Max. 1 art.)	2
	Cardio Thoracic (CABG ven gr or max. 1 art. Gra)	7
	Cardio Thoracic (Re-CABG)	14
	Coronary artery disease	6
	Cardio Thoracic (Maze Procedure)	5
	Total All Cardiac	670
Endocrinology	Acute Kidney Injury	2
	Addison's Disease	6
	Anemia	3
	Diabetes	1
	Diabetes mellitus	3
	Diabetes Mellitus (Uncontrolled)	10
	Diabetic ketoacidosis	1
	Hyperkalemia	1
	Hypocalcemic crisis	1
	Hypoxemia	1
	Inaugural diabetes	1
	Total Endocrinology	30
Gastroenterological	Acute on chronic liver failure	2

Medical Condition Category	Medical Condition Sub-category/ Reason for Hospitalization	# of Patients
	Adhesive bowel obstruction	2
	Bleeding bulbar ulcer	4
	Bleeding oesophageal varices	1
	Constipation	8
	Diaphragmatic hernia	1
	Diarrhea	17
	Digestive obstruction	1
	Diverticular peritonitis	1
	Gastric ulcer perforated	1
	Hepatitis	1
	Observation: Abdominal Discomfort	3
	Pancreatitis	10
	Peritonitis	7
	Small bowel obstruction	1
	Umbilical Hernia	1
	Total Gastroenterological	61
Miscellaneous	Blood Transfusion	1
	Hospitalization by Intensivist (Disease Status Not Given)	4
	Hospitalization for internal medicine (other reasons)	15
	Hospitalization for internal medicine (other surgical reasons)	1
	Nausea/vomiting	2
	Observation: Pediatrics	1
	Total Miscellaneous	24
Neuro-Trauma	Acute Brain Injury (Aneurysm)	6
	Acute Brain Injury (Hematoma-Drilling)	1
	Brain hemorrhage	36
	Brain trauma	3
	Chronic subdural hematoma	1
	Fractured Vertebrae	1
	Neuro-trauma	33
	Seizures	3
	Stroke	10
	Subarachnoidal hemorrhage	1
	Subdural hematoma	1
	Total Neuro-Trauma	96
Neurological	Altered consciousness	1
	Confusion	1
	Hypercapnic encephalopathy	2
	Muscular dystrophy (Pompe disease)	1
	Myopathy (Pompe disease)	1

Medical Condition Category	Medical Condition Sub-category/ Reason for Hospitalization	# of Patients
	Observation: Neurological	16
	Observation: Psychiatrics	1
	Sacral meningocele dural fistula	1
	Tetraplegia ankylosing spondylitis	1
	Total Neurological	25
Obstetrics/ Gynecological	Cesarean Section	26
	Dilatation & Curettage	1
	Gemellary pregnancy	1
	Gemellary Pregnancy Delivery	1
	Observation: Primary Cesarean Section	3
	Obstetric hemorrhage Atonic uterus	1
	Obstetrics (pre-term labor)	17
	Ovarian hyperstimulation syndrome	1
	Postpartum hemorrhage Placental retention	2
	Pre Eclampsia	2
	Pregnancy associated vomiting	4
	Refractory vomiting in pregnancy	1
	Stall Wife After Parturition	44
	Fistula Revision	1
	Total Obstetrics/Gynecological	105
Oncology	Acute Lymphocytic Leukemia w/ Tumor Lysis Syndrome	2
	Acute Myeloid Leukemia	16
	AIDS Cerebral lymphoma	1
	Ampullary Adenocarcinoma	1
	Ampullary tubular Pancreatic Adenoma	1
	Bile Duct and Gallbladder Adenocarcinoma	1
	Bladder Cancer	3
	Brain metastasis	1
	Brain metastasis from mammary cancer	1
	Carcinoma of the mouth	1
	Carcinomatous peritonitis from ovarian sarcoma resection	1
	Central Nervous System Lymphoma	1
	Chemotherapy	22
	Cholangiocarcinoma	3
	Chronic Lymphocytic Leukemia	1
	Chronic lymphoid leukemia	1
	Chronic Myelomonocytic Leukemia (CMML) Type 2	1
	Colorectal cancer	1
	Distal Esophageal Adenocarcinoma	3

Medical Condition Category	Medical Condition Sub-category/ Reason for Hospitalization	# of Patients
	Laryngeal cancer	2
	Lung Cancer w/pleural	1
	Lung carcinoma	4
	Mantle Cell Lymphoma	2
	Meningioma	1
	Metastatic Non-Small Cell Lung Cancer (NSCLC) 3	3
	Mucinous Adenocarcinoma	2
	Multiple Myeloma	3
	Neuroendocrine (pancreas)	2
	Obstructive laryngeal cancer	1
	Oesophageal leiomyoma	1
	Ovarian Cancer	1
	Pancreatic cancer	1
	Pancreatic Ductal Adenocarcinoma	1
	Peritoneal carcinomatosis	2
	Thyroid Cancer	1
	Prostate stromal sarcoma	1
	Pulmonary cancer	2
	Pulmonary metastasis from colic adenocarcinoma	1
	Rectal Cancer	3
	Relapsed T cell prolymphocytic leukemia	1
	Small cell lung carcinoma	1
	T Cell Lymphoma	1
	Brain tumor resection	1
	Total Oncology	101
Oncology Surgical	Cerebral metastasis resection	1
	Colon cancer surgery	11
	Gastrectomy for gastric cancer	1
	Glossectomy for cancer	1
	Lipoma surgical removal	1
	Neoplastic colonic obstruction	1
	Pulmonary bilobectomy for lung cancer	1
	Lung lobectomy	6
	Pneumonectomy for cancer	2
	Supra cellar meningioma surgery	1
	Temporal meningioma removal surgery	1
	Total Oncology Surgical	27
Pulmonary	Acute lung edema	4
	Acute Respiratory Distress Syndrome	1
	Asthmatic crisis	2
	Hemoptysis	1

Medical Condition Category	Medical Condition Sub-category/ Reason for Hospitalization	# of Patients
	Chronic Obstructive Pulmonary Disease (COPD) exacerbation	28
	Dyspnea (respiratory distress)	32
	Hyperventilation	1
	Idiopathic pulmonary fibrosis	3
	Observation: Pulmonologist	2
	Pneumocystis jiroveci pneumonia	3
	Pneumonia	62
	Pneumothorax	4
	Pseudomonas aeruginosa bilateral pneumonia	1
	Pulmonary Embolism	11
	pulmonary hypertension	2
	Respiratory failure	4
	Total Pulmonary	161
Renal	Acute on chronic renal failure	2
	Chronic Kidney Disease	6
	End Stage Renal Disease	3
	Hematuria	10
	Renal failure	1
	Renal Insufficiency	5
	Total Renal	27
Sepsis and Infection	Acquired Immune Deficiency Syndrome (AIDS)	10
	Cirrhosis	6
	Erysipelas (Acute Infection)	7
	Fever of unknown origin	1
	General Malaise	3
	Hemorrhagic shock	2
	Liver cirrhosis	1
	Meningitis	3
	Meningoencephalitis	1
	Osteitis	1
	Sepsis	17
	Sepsis (Urological Origin)	6
	Septicemia	2
	Severe Malaria (falciparum)	1
	Toxic coma	1
	Tuberculous meningitis	2
	Tuberculous pneumonia	1
	Urinary Tract Infection	5
	Urological Catheter and AWES (Ambulatory Wireless ECG Sensor)	1
	Urosepsis	2

Medical Condition Category	Medical Condition Sub-category/ Reason for Hospitalization	# of Patients
	Variceal bleeding cirrhosis	2
	Wound Infection	4
	Total Sepsis and Infection	90
Suicide	Tentative Suicide/Suicide	7
Surgical General	Acoustic schwannoma resection	1
	Bariatric surgery body mass index (BMI)	3
	Cervical schwannoma	2
	Decortication Surgery	7
	Hip Dislocation	1
	Hip Replacement	1
	Morbid obesity	1
	Nephrectomy transabdominal	1
	Observation: Surgery	12
	Percutaneous Endoscopic Gastronomy Catheter Placement	1
	Abdominal Surgery	15
	Craniotomy	7
	Pharyngolaryngectomy	1
	Lung Surgery	6
	Pulmonary nodule resection	1
	Meningeal leak closure	1
	Pontocerebellar arachnoidal cyst removal	1
	Subdural hematoma removal surgery	1
	Surgical removal of a schwannoma of the VIII	1
	Postoperative gastric by-pass for obesity peritonitis	2
	Multinodular thyroid goiter	1
	Kidney Transplant	2
	Total Surgical General	71
Trauma	Abdominal stab wound	1
	Carbamazepine overdose	1
	Coma	1
	Drug overdose	1
	Drug overdose coma	1
	Femoral fracture	1
	Head trauma	13
	Leg trauma	1
	Methadone alcohol overdose	2
	Multiple trauma	13
	Observation (Emergency Dept	1
	Pelvic fracture	1
	Polytrauma	5

Medical Condition Category	Medical Condition Sub-category/ Reason for Hospitalization	# of Patients
	Thoracic trauma	1
	Trauma	18
	Traumatic coma	1
	Total Trauma	62

Medications:

During the study, participants received approximately 8000 medications representing over 30 parent drug classes and over 140 drug subclasses (with as many as 68 different drugs administered to each patient). The parent drug classes (bolded) and the subclass distribution in the clinical study can be found in the table below along with the number of patients that received each sub-class of drugs:

Parent Drug Classes	Drug Sub-Classes	# of Patients
Alcohol	Alcohol	1
Anti-Infective	Quinolones	6
	Anthelmintics	5
	Antibiotic	970
	Anti-fungal	515
	Anti-malarial	10
	Anti-tuberculosis	2
	Anti-Viral	99
	Anti-Viral Protease Inhibitors	78
Antidote	Antidote	32
Anti-Neoplastic	Alkylating Agent	2
	Anti-metabolites	5
	Monoclonal Antibodies	8
	VEGF (Vascular endothelial growth factor) Inhibitors	1
Anti-Psoriatics	Vitamin A Retinoid	3
Disease Modifying Anti-Rheumatic	Anti-Rheumatic	1
Anti-Vertigo	Anti-Vertigo	3
Biologicals	Recombinant Human Erythropoietins	27
Blood Products	Plasma	11
	Platelets	6
	Red Blood Cells	29
Calcimimetic	Calcium Receptor	11
Cardiovascular Agents	ACE (angiotensin-converting-enzyme) Inhibitor / Diuretic	1
	ACE Inhibitors	364

	Alpha-adrenergic Blockers	21
	Angiotensin II Inhibitors	93
	Antiadrenergic	197
	Antidysrhythmic	380
	Antihypertensive	22
	Beta Blocker	556
	Calcium Channel Blocker	328
	Diuretic	741
	Inotropes	300
	Vasodilator	376
	Vasopressors	68
	Vasopressors or Inotropics	367
Cholinergic Muscle Stimulant Agents	Choline Thick Stimulant	1
Central Nervous System Agents	5HT3 Antagonist Antiemetic	185
	Anaesthetic	465
	Analgesic – NSAID (non-steroidal anti-inflammatory drug)	947
	Analgesics - narcotic	840
	Anticholinergic	40
	Anticonvulsant	140
	Antiemetic	71
	Anti-Parkinson	10
	Benzodiazepines	719
	Muscle Relaxer	138
	Sedative	7
	Stimulants	2
Coagulation Modifiers	Anticoagulants	957
	Anti-platelet	30
	Thrombolytics	142
Radiologic Agent	Contrast Agents	4
Gastrointestinal	Antacid	91
	Antacid and Electrolyte	2
	Antidiarrheals	13
	Antispasmodic	4
	Digestive enzymes	11
	Gallstone Solubilizing Agents	12
	Gastrointestinal Deamination	400
	Gastrointestinal Stimulant (also used as antiemetic)	376

	H-2 Antagonist	229
	Laxative	611
	Laxative / Antacid	61
	Protectant	8
	Proton-pump Inhibitor	754
Genitourinary	Antispasmodic	15
	PDE5 (phosphodiesterase type 5 inhibitor) Inhibitor	10
Hemodialysis	Hemodialysis	6
Hormonal	Glucocorticoids	467
	Hormone - Sex	175
	Hormone	3
	Hormone - growth	6
	Hormone - peptide	99
	Hormone - Pituitary	1
	Hormone - Polypeptide	3
	Hormone - Thyroid	60
	Hormone- Antidiuretic	71
	Insulin – Injectable and Oral	705
	Somatostatine Analog	15
Hyperkalemia Agent	Uncategorized Agent used to treat Hyperkalemia (High Potassium)	40
Immunologic Agent	Immunoglobulins	3
	Immunostimulants	4
	Immunostimulants –Vaccine	3
	Immunosuppressant	32
Metabolic/Nutritional	Glucose Elevating / Electrolyte	58
	Anti-diabetic	100
	Anti-hyperlipidemic	16
	Anti-hyperuricemic	19
	Bisphosphonates	55
	Glucose Elevating Agent	177
	Statin	433
Nutritional Product	Amino Acid	100
	Electrolyte	81
	Herbal Supplement	7
	Iron	52
	Mineral / Electrolyte	685
	Multivitamin	94
	Vitamin	15

	Vitamin / Mineral	351
	Vitamin B	54
	Vitamin B-12	20
	Vitamin B-6	2
	Vitamin C	113
	Vitamin D	38
Phosphate Binder	Phosphate Binder	41
Plasma Expander	Blood Products	36
	Gelatin	1
	Globular Proteins	104
	Plasma Replacement	3
	Starch	46
Psychotherapeutic Agent	Antidelirium	12
	Antidepressants	79
	Antipsychotic - Atypical	68
	Antipsychotic - Non-phenothiazine	221
	Antipsychotic - Phenothiazines	5
	Bipolar Agent	40
Respiratory	Antihistamine	175
	Bronchodilator	636
	Decongestant	22
	Expectorant	12
	Leukotriene modifier	1
	PDE4 Inhibitors	1
Smoking Cessation Agents	Smoking Cessation Agents	45
Topical Agents	Anti-hemorrhagic	54
	Antimicrobial Irrigation	66
	Dental and Oral Agents	118
	Dermatological Crèam	10
	Dermatological Powder	78
	Emollients	95
	Hydrating Eye Ointment	179
	Medicated Ointment	248
	Medicated Ophthalmic Drops	40
	Medicated Ophthalmic Drops and Steroid	11
	Nasal Antibiotic	116
	Nasal Decongestant	2
	Nasal Steroid	10

	Ophthalmic Diagnostic Agent	1
	Ophthalmic Glaucoma Agent	20
	Ophthalmic Medicated Steroid	6
	Ophthalmic Preparation	5
	Topical Photochemotherapeutics	4
Topical Anti-Infective	Antibiotic Crème	3
	Dermatological Antibacterial	90

CLIA WAIVER

The Nova StatStrip Glucose Hospital Meter System previously obtained CLIA WAIVER by application on February 28, 2008. The study performed to support CLIA waiver for this device was reanalyzed to evaluate whether the arterial and venous data would meet new and clinically appropriate Limits of Erroneous Results (LER) and Allowable Total Error (ATE) for the sponsor’s new intended use population (all hospitalized patients). The analysis demonstrates that the previous CLIA Waived studies in venous and arterial whole blood meet appropriate waiver standards for hospitalized patients. The percentage of arterial and venous data over the entire measurement range that falls within the ATE zone is 98.4% (363/369). None of the results were in the LER zone.

Therefore, the sponsor’s CLIA waived status is extended to cover the new intended use claims cleared in this current submission.

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 _____ or No X .

2. Software:

As established in k060345 and k063821. No changes were made to the software in this submission.

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. Clorox Germicidal Wipes, EPA registration # 67619-12 was validated demonstrating complete inactivation of live virus for use with the meter. The sponsor also 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) to simulate 3 years of device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.
- 5) Certificates of Electromagnetic Compatibility (EMC) as established in k060345.
- 6) Customer Care Service Center is available by calling 800-345-6682.

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.