510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

k193246

B Applicant

Nova Biomedical Corporation

C Proprietary and Established Names

Stat Profile Prime Plus Analyzer System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CHL	Class II	21 CFR 862.1120 - Blood gases (pCO_2, pO_2) and blood pH test system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modification of a previously cleared device (k173797) – modify the intended use of the device to include Point-of-Care (POC) use.

B Measurand:

pH, pO_2 and pCO_2.

C Type of Test:

pH and pCO_2 – quantitative, potentiometry
pO_2 – quantitative, amperometric technology

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings and for point-of-care usage for quantitative determination of pH, Partial Pressure of Carbon Dioxide (pCO2), and Partial Pressure of Oxygen (pO2) in heparinized arterial and venous whole blood.

pH, pCO_2 and pO_2 measurements are used in the diagnosis and treatment of life-threatening acid base disturbances.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For clinical laboratory and point of care use.

D Special Instrument Requirements:

Stat Profile Prime Plus Analyzer System

IV Device/System Characteristics:

A Device Description:

The Stat Profile Prime Plus Analyzer System is a small automatic blood gas analyzer for laboratory and point of care setting. It consists of the analyzer, sensor cartridges, calibrator packs, auto-cartridge quality control packs (internal controls), ampuled quality control materials (external controls) and thermal paper for an onboard printer. Specimens may be identified by scanning a barcode or by manually entering the information via the touchscreen.

The Stat Profile Prime Plus Analyzer has slots to accommodate two sensor cartridges (Primary and Auxiliary). The analyzer will determine the configuration of the system by detecting which sensor cards are installed. The reporting of CO-Oximeter parameters (or not reporting them) will also be determined by the selection of the Sensor Cards, for which there are two options:

- Primary Sensor Card 1 reports the following analytes: pO_2, pCO_2, pH, Hct, tHb, Na, Cl, K, iCa, iMg, Glu, SO_2, O_2Hb, COHb, MetHb, HHb, tBil, HbF
- Primary Sensor Card 2 reports the following analytes: pO_2, pCO_2, pH, Hct, tHb, Na, Cl, K, iCa, iMg, Glu, SO_2

B Principle of Operation:

pH: pH is measured using a hydrogen ion selective glass membrane. One side of the glass is in contact with a solution of constant pH. The other side is in contact with a solution of unknown pH. A change in potential develops which is proportional to the pH difference of these solutions. This change in potential is measured against a reference electrode of constant potential. The magnitude of the potential difference is a measure of the pH of the unknown sample.

pCO_2: pCO_2 is measured with a modified pH sensor. Carbon dioxide in the sample makes contact with a gas permeable membrane mounted on a combination measuring/ reference electrode. CO_2 diffuses across the membrane into a thin layer of electrolyte solution in response to partial pressure difference. This solution then becomes equilibrated with the external gas pressure. CO_2 in the solution becomes hydrated producing carbonic acid, which results in a change in hydrogen ion activity, according to the equation:

$$CO_2 + H_2O <=> H_2CO_3 <=> H^+ + [HCO_3^-]$$

The electrolyte solution behind the membrane is in contact with a glass hydrogen ion selective sensor. The change in hydrogen ion activity in the electrolyte solution produces a potential which is measured against the internal filling solution. This change in potential is measured against the constant potential of the reference electrode half-cell and is logarithmically related to the pCO2 of the unknown sample.

pO_2: pO_2 is measured amperometrically by the generation of a current at the sensor surface. As oxygen diffuses through a gas permeable membrane, the oxygen molecules are reduced at the cathode, consuming 4 electrons for every molecule of oxygen reduced. This flow of electrons is then measured by the sensor and is directly proportional to the partial pressure of oxygen in the sample.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Stat Profile Prime Plus Analyzer System

B Predicate 510(k) Number(s):
k173797

C Comparison with Predicate:

Device & Predicate Device(s):	k193246	k173797
Device Trade Name	Stat Profile Prime Plus Analyzer	Stat Profile Prime Plus Analyzer
General Device Characteristic Similarities		
Intended Use/Indications for Use	For in vitro diagnostic use for the determination of pH, Partial Pressure of Carbon Dioxide, and Partial Pressure of Oxygen in heparinized arterial and venous whole blood.	Same
Acceptable Sample Types	Lithium heparin whole blood from syringes and open tubes.	Same
Sample Volume	135 µL	Same
General Device Characteristic Differences		
Settings for use	Clinical laboratories and point-of-care settings	Clinical laboratories

VI Standards/Guidance Documents Referenced:

CLSI EP05-A2 – Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition.

IEC 61010-1:2010 – Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements.

IEC 60601-1-2:2014 – Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests.

VII Performance Characteristics:

A Analytical Performance:

1. Precision/Reproducibility:
   Three separate studies were conducted to evaluate the precision of Stat Profile Prime Plus Analyzer the for pH, pCO_2 and pO_2. The studies were conducted at three point of care (POC)

sites including a Cardiothoracic Intensive Care Unit, an Emergency Department and a Respiratory Therapy Lab. A total of 61 respiratory care, 12 nursing, and 1 exercise physiology POC personnel participated from the 3 POC settings over the course of the studies.

a) Within-Run Precision

Within-run precision of the Stat Profile Plus Analyzer System in the hands of POC operators was assessed using a combination of three levels of Quality Control (QC) material and two levels of linearity materials to cover the measuring range for each analyte. Each sample was analyzed in replicates of 20 using three Stat Profile Plus Analyzer Systems. All three POC sites produced similar results. Representative within-run precision results from one site are summarized in the table below:

Within Run Precision with Controls and Linearity Materials – one representative POC site

Within-Run Precision						
Parameter	n=20	Level 1 QC	Level 2 QC	Level 3 QC	Level 1 LN	Level 2 LN
pH	Mean	7.227	7.420	7.616	6.754	7.726
	SD	0.008	0.003	0.006	0.012	0.004
	% CV	0.12	0.04	0.07	0.18	0.05
pCO_2 (mm Hg)	Mean	63.2	38.9	20.2	118.6	18.7
	SD	2.2	0.7	0.2	3.9	0.1
	% CV	3.4	1.9	1.0	3.3	0.5
pO_2 (mm Hg)	Mean	78.2	115.0	145.7	44.7	476.4
	SD	1.1	1.2	2.5	2.2	6.4
	% CV	1.5	1.0	1.7	4.9	1.3

b) Total Imprecision

Total imprecision of the Stat Profile Prime Plus Analyzer System in the hands of POC operators was assessed using three levels of QC materials and three Stat Profile Plus Analyzer Systems. For each run, each sample was run in duplicate each day for a total of 20 days (a total of 40 results on each of the three Stat Profile Prime Plus Analyzers). All three POC sites produced similar results. Representative total imprecision results from one site are summarized in the table below:

Total Imprecision – one representative POC site

	n	Mean	Within Run SD	Within Run %CV	Total SD	Total %CV
Level 1 QC						
pH	40	7.223	0.004	-	0.008	-
pCO_2 (mmHg)	40	60.0	1.6	2.6	3.6	5.9
pO2 (mmHg)	40	76.5	1.3	1.6	2.4	3.1
Level 2 QC						
pH	40	7.428	0.003	-	0.006	-
pCO_2 (mmHg)	40	37.2	1.1	3.0	2.3	6.1
pO_2 (mmHg)	40	112.2	1.6	1.4	3.0	2.6
Level 3 QC						
pH	40	7.627	0.006	-	0.008	-
pCO_2 (mmHg)	40	20.1	0.6	3.1	1.0	4.8
pO_2 (mmHg)	40	148.9	1.6	1.1	3.4	2.3

c) Precision using whole blood samples

A whole blood within-run precision study was performed at three POC sites by two POC operators using one Stat Profile Prime Plus Analyzer System at each site. Five fresh, native arterial whole blood samples were analyzed in replicates of ten. Each whole blood specimen was maintained in a syringe for the duration of the testing. The POC operator performed all sample analysis steps including sample analysis, removal of resultant air bubble(s) from the syringe, recapping of the syringe and mixing prior to the next sample analysis. The results from each site are presented in the tables below.

Point of care site 1

Analyte	Sample	N	Mean	SD	%CV
pH	1	10	7.342	0.003	-
	2	10	7.389	0.005	-
	3	10	7.293	0.002	-
	4	10	7.384	0.002	-
	5	10	7.465	0.005	-
pCO_2 (mmHg)	1	10	44.3	1.59	3.58
	2	10	34.5	0.36	1.03
	3	10	37.7	0.27	0.71
	4	10	24.4	0.67	2.77
	5	10	27.9	0.24	0.85
pO_2 (mmHg)	1	10	41.8	0.23	0.56
	2	10	80.8	1.01	1.25
	3	10	338.2	13.48	3.98
	4	10	41.2	0.45	1.08
	5	10	150.1	5.04	3.36

Point of care site 2

Analyte	Sample	N	Mean	SD	%CV
pH	1	10	7.287	0.011	-
	2	10	7.282	0.003	-
	3	10	7.405	0.005	-
	4	10	7.347	0.006	-
	5	10	7.396	0.003	-
pCO_2 (mmHg)	1	10	50.6	0.82	1.62
	2	10	19.7	0.26	1.31
	3	10	31.0	0.22	0.70
	4	10	38.2	0.33	0.86
	5	10	34.5	0.39	1.14
pO_2 (mmHg)	1	10	57.9	0.46	0.80
	2	10	66.7	1.34	2.01
	3	10	91.4	1.72	1.88
	4	10	643.0	30.44	4.73
	5	10	84.0	1.62	1.93

Point of care site 3

Analyte	Sample	N	Mean	SD	%CV
pH	1	10	7.390	0.002	-
	2	10	7.287	0.002	-
	3	10	7.513	0.004	-
	4	10	7.230	0.002	-
	5	10	7.160	0.002	-
pCO_2 (mmHg)	1	10	34.3	0.47	1.38
	2	10	48.9	0.69	1.40
	3	10	18.3	0.18	0.99
	4	10	50.3	0.99	1.97
	5	10	63.8	1.27	2.00
pO_2 (mmHg)	1	10	101.7	0.61	0.60
	2	10	42.7	0.35	0.81
	3	10	147.4	2.12	1.44
	4	10	74.2	1.14	1.54
	5	10	44.7	0.34	0.75

2. Linearity:

   Previously established in k173797.

3. Analytical Specificity/Interference:

   Previously established in k173797.

4. Assay Reportable Range:

   Previously established in k173797.

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

   Previously established in k173797.

6. Detection Limit:

   Previously established in k173797.

7. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Method comparison studies were conducted at three POC sites - a Cardiothoracic Intensive Care Unit, an Emergency Department and a Respiratory Therapy Lab. Lithium heparinized arterial and venous whole blood specimens were analyzed in singlet using three Stat Profile Prime Plus analyzers (one at each site) by 65 POC staff members (13, 21 and 31 POC staff members within each testing site, respectively, including a total of 52 respiratory care, 12 nursing, and 1 exercise physiology POC personnel). In order to cover the claimed measuring range for each analyte, less than 10% of samples for each analyte were altered. The clinical results obtained by POC staff members were compared to results obtained by trained healthcare professionals from the same whole blood specimens. Each of the three sites produced similar method comparison data. Linear regression analysis for venous and arterial whole blood method comparison for all POC sites combined is presented in the table below.

Venous and arterial whole blood method comparison – POC vs. Laboratory Operators (combined sites)

Analyte	n	Sample concentration range	Slope	Intercept	r
pH	432	6.832-7.931	0.9930	0.0050	0.9976
pCO_2 (mm Hg)	432	14.0-199.2	0.9848	0.9958	0.9963
pO_2 (mm Hg)	428	11.5-565.2	1.0109	-1.5391	0.9989

2. Matrix Comparison:

   Not applicable. The only acceptable sample type for this device is lithium heparin whole blood.

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):

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Reference ranges for pH, pCO_2 and pO_2 are cited from literature[1, 2, 3]:
pH: 7.350 - 7.450 (pH units)
pCO_2: 35 - 45 mm Hg
pO_2: 83 - 108 mm Hg

1. Statland, Bernard, Clinical Decision Levels for Lab Tests, Medical Economics Books, 1987.

2. Burtis, Carl A. and Ashwood, Edward R., ed. 1994. Tietz Textbook of Clinical Chemistry, W. B. Saunders Co. Philadelphia, PA.

3. Tietz, Norbert W., ed. 1983. Clinical Guide to Laboratory Tests, W. B. Saunders Co., Philadelphia, PA.

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.