510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

k200204

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
GGZ	Class II	21 CFR 864.7500 - Whole Blood Hemoglobin Assays	HE - Hematology
GHS	Class II	21 CFR 864.7425 - Carboxyhemoglobin assay	HE - Hematology
GKK	Class II	21 CFR 864.7500 - Whole blood hemoglobin assays	HE - Hematology
GKR	Class II	21 CFR 864.5620 - Automated hemoglobin system	HE - Hematology
JPI	Class II	21 CFR 864.6400 - Hematocrit measuring device	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

Modification of a previously cleared device (k180186) – modify the intended use of the device to include Point-of-Care (POC) use.

B Measurand:

Hematocrit (Hct), Oxygen Saturation (sO_2), Total Hemoglobin (tHb), Oxyhemoglobin (O_2Hb), Carboxyhemoglobin (COHb), Methemoglobin (MetHb), and Deoxyhemoglobin (HHb)

C Type of Test:

Hct: quantitative, impedance sensor
sO_2, tHb, O_2Hb, COHb, MetHb, HHb: quantitative, spectrophotometric

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 Hematocrit, Oxygen Saturation, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, and Deoxyhemoglobin in heparinized arterial and venous whole blood.

Hematocrit (Hct) measurements of the packed red blood cell volume are used to distinguish normal from abnormal states, such as anemia and erythrocytosis.

Oxygen Saturation (sO2) measurements are used to assess the oxygenation of the hemoglobin and the adequacy of tissue oxygenation in the evaluation of pulmonary function. Measurements are also used to diagnose and treat cyanosis.

Total Hemoglobin (tHb) measurements are used in the evaluation of chronic and acute anemia as well as the oxygen transport capability of the hemoglobin.

Oxyhemoglobin (O2Hb) measurements are used to assess pulmonary function in combination with Deoxyhemoglobin and are also used in the diagnosis and treatment of cyanosis.

Carboxyhemoglobin (COHb) measurements are used to determine if and to what level carbon monoxide has been inhaled by the patient. High levels of carbon monoxide can lead to tissue anoxia and death.

Methemoglobin (MetHb) measurements are used to determine congenital methe- moglobinemia or determine the ingestion of nitrates, chlorates, or any other drug or chemical that can cause methemoglobin formation. High levels of methemoglobin can lead to cyanosis and death.

Deoxyhemoglobin (HHb) measurements are used to assess pulmonary function in combination with Oxyhemoglobin.

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, Na, Cl, K, iCa, iMg, Glu, tBil, Hct, tHb, sO_2, O_2Hb, COHb, MetHb, HHb

• Primary Sensor Card 2 reports the following analytes: pO_2, pCO_2, pH, Na, Cl, K, iCa, iMg, Glu, Hct, tHb, sO_2

B Principle of Operation:

Oxygen saturation (sO_2) represents the percent of hemoglobin bound to oxygen, expressed as a fraction of the amount of hemoglobin capable of binding to oxygen (oxyhemoglobin plus deoxyhemoglobin). As the level of SO_2 changes within a blood sample, the optical absorbance of the whole blood changes.

Hematocrit (Hct) is defined as the percentage of red blood cells to the total blood volume and is measured by the electrical resistance of the blood sample. The hematocrit value is corrected for the concentration of the sodium ion.

Total Hemoglobin (tHb) is measured by optical absorbance, and is the sum of all measured hemoglobin fractions expressed as the amount of hemoglobin in a specified volume of whole blood.

Oxyhemoglobin (O_2Hb) is measured by optical absorbance, and is the combined form of hemoglobin and oxygen.

Carboxyhemoglobin is measured by optical absorbance, and is the combined form of carbon monoxide and hemoglobin.

Methemoglobin is measured by optical absorbance, and is the form of hemoglobin in which the iron has been oxidized from the ferrous to the ferric state.

Deoxyhemoglobin is measured by optical absorbance, and is the form of hemoglobin that is not combined with oxygen but can easily uptake oxygen in the lungs.

V Substantial Equivalence Information:

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

B Predicate 510(k) Number(s):
k180186

C Comparison with Predicate(s):

Device & Predicate Device(s):	k200204	k180186
Device Trade Name	Stat Profile® Prime Plus Analyzer System	Stat Profile® Prime Plus Analyzer System
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the quantitative determination of Hematocrit, Oxygen Saturation, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, and Deoxyhemoglobin 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:

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 (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The precision performance of the Stat Profile® Prime Plus Analyzer System for Hct, sO_2, tHb, O_2Hb, COHb, MetHb, and HHb for POC use was established in three separate studies using methods described in CLSI EP5-A2. The studies were conducted at three POC sites: a Cardiothoracic Intensive Care Unit, an Emergency Department and a Respiratory Therapy Lab. Across all three studies, a total of 61 respiratory care, 12 nursing, and 1 exercise physiology POC personnel participated.

Within-run precision using controls
A three site POC within-run precision (repeatability) study of the Stat Profile® Plus Analyzer System for Hct, SO_2, tHb, O_2Hb, COHb, MetHb, and HHb was conducted by testing three levels of quality control material and/or two levels of linearity materials. At each site, the samples were assayed in replicates of 20 using one analyzer for a total of three Stat Profile® Plus Analyzer Systems and 60 measurements per sample. All three POC sites produced similar results. Representative within-run precision results from one site are summarized in the tables below:

Hct (%)	
Mean	**SD**
61	0.7
38	0.3
26	0.6
29	0.2
46	0.004

sO2 (%)	
Mean	**SD**
48	0.9
78	0.01
90	0.5

tHb (g/dL)		
Mean	**SD**	**%CV**
20.0	0.1	0.7
12.8	0.1	0.9
6.4	0.1	1.7

O2Hb (%)		
Mean	**SD**	**%CV**
21.0	0.4	2.0
47.3	0.1	0.3
80.1	0.1	0.1

COHb (%)		
Mean	**SD**	**%CV**
29.0	0.3	0.9
21.7	0.2	1.0
6.6	0.1	1.6

MetHb (%)		
Mean	**SD**	**%CV**
27.4	0.1	0.4
17.5	0.3	1.7
5.0	0.2	4.0

HHb (%)		
Mean	**SD**	**%CV**
22.6	0.2	0.9
13.5	0.1	0.9
8.4	0.2	1.9

Within-run precision using whole blood
A three site POC within-run precision (repeatability) study of the Stat Profile® Plus Analyzer System for Hct, sO_2, tHb, O_2Hb, COHb, MetHb, and HHb was conducted by testing five levels of analytes in native whole blood samples and two levels of analytes in altered whole blood samples. At each site, the samples were assayed in replicates of 10 using one analyzer for a total of three Stat Profile® Plus Analyzer Systems and 30 measurements per sample. A minimum of two operators at each site for a total of 9 operators conducted the testing. The results from each site are presented in the tables below.

Hct (%)

Site	**Mean**	**SD**
1	46.5	0.71
	46.6	0.52
	43.9	0.57
	30.0	0.47
	35.2	0.42
	44.7	0.82
	43.6	0.52
2	48.4	1.43
	20.8	0.42

Site	Mean	SD
	49.6	0.70
	49.8	0.63
	26.7	0.48
	38.1	0.57
	44	0.47
	48.4	1.43
3	46	0.00
	48.8	0.79
	48	0.00
	38.9	0.32
	44	0.47
	44.1	0.32
	46.3	0.82

sO_2 (%)

Site	Mean	SD
1	50.0	0.94
	66.4	0.70
	92.3	0.48
	92.5	0.53
	93.8	0.42
	97.1	0.32
	99.0	0.00
2	80.0	0.00
	89.4	0.7
	92.5	0.53
	95.9	0.32
	98.9	0.32
	99.4	0.52
	99.4	0.52
3	44.0	0.00
	53.6	0.97
	85.1	0.32
	91.0	0.00
	95.1	0.32
	95.9	0.32
	97.9	0.32

tHb (g/dL)

Site	Mean	SD	%CV
1	16.2	0.05	0.3
	16.1	0.05	0.3
	14.9	0.05	0.3
	8.4	0.08	0.9
	10.3	0.09	0.9
	15.6	0.19	1.2

Site	Mean	SD	%CV
	15.4	0.16	1.0
2	15	0.31	2.1
	7.2	0.22	3.0
	16.2	0.05	0.3
	16.1	0.05	0.3
	8.2	0.05	0.6
	11	0.12	1.1
	14.7	0.08	0.5
3	14.4	0.05	0.3
	17	0.00	0.00
	16.5	0.07	0.4
	11.5	0.07	0.6
	14	0.12	0.8
	14.8	0.07	0.5
	15.8	0.37	2.4

O_2Hb (%)

Site	Mean	SD	%CV
1	49.6	0.48	1.0
	64.5	0.73	1.1
	66.9	0.35	0.5
	78.9	0.27	0.3
	91.8	0.53	0.6
	95.5	0.28	0.3
	98.3	0.21	0.2
2	60.50	1.01	1.7
	78.60	0.30	0.4
	85.00	0.65	0.8
	90.40	0.45	0.5
	93.90	0.48	0.5
	94.40	0.17	0.2
	97.70	0.13	0.1
3	42.6	0.31	0.7
	44.0	0.00	0.00
	52.8	0.86	1.6
	66.8	0.92	1.4
	76.1	0.26	0.3
	83.1	0.46	0.6
	94.1	0.46	0.5

COHb (%)

Site	Mean	SD	%CV
1	0.38	0.08	20.8
	0.38	0.08	20.8
	0.95	0.33	34.8

Site	Mean	SD	%CV
	1.10	0.16	14.8
	1.92	0.19	10.1
	14.3	0.27	1.9
	15.4	0.20	1.3
	1.08	0.17	15.7
	1.28	0.25	19.5
	1.53	0.27	17.6
2	1.60	0.19	11.9
	4.11	0.17	4.0
	4.74	0.15	3.2
	17.40	0.21	1.2
	0.38	0.06	15.8
	0.39	0.09	23.1
	0.70	0.34	48.6
3	0.73	0.24	32.9
	0.80	0.24	30.0
	15.8	0.26	1.7
	16.2	0.31	1.9

MetHb (%)

Site	Mean	SD	%CV
	0.42	0.09	21.9
	0.43	0.08	19.2
	0.43	0.09	22.1
1	0.44	0.08	19.2
	0.62	0.23	36.3
	0.79	0.14	18.3
	13.23	0.23	1.71
	0.38	0.08	21.0
	0.54	0.08	14.8
	0.58	0.09	15.5
2	0.71	0.07	9.8
	0.81	0.22	27.2
	0.88	0.15	17.0
	21.50	1.06	4.9
	0.77	0.12	15.6
	0.80	0.08	10.0
	0.90	0.14	15.6
3	1.00	0.08	8.0
	1.20	0.11	9.2
	1.40	0.12	8.6
	13.60	0.79	5.8

HHb (%)

Site	Mean	SD	%CV
1	0.9	0.19	21.6
	2.7	0.14	5.4
	4.5	0.18	4.0
	6.5	0.19	2.9
	7.4	0.44	5.9
	32.9	0.69	2.1
	49.0	0.38	0.8
2	0.48	0.08	16.6
	0.50	0.11	22.0
	0.61	0.18	29.5
	4.00	0.36	9.2
	7.20	0.37	5.1
	10.10	0.60	6.0
	19.60	0.18	0.9
3	2.30	0.16	6.9
	3.41	0.14	4.0
	4.30	0.14	3.2
	7.38	0.14	1.9
	14.70	0.51	3.4
	46.00	0.87	1.9
	54.50	0.33	0.6

Total precision

A three site POC total precision study of the Stat Profile® Prime Plus Analyzer for Hct, sO_2, tHb, O_2Hb, COHb, MetHb, and HHb was conducted using three levels of QC materials and one Stat Profile® Plus Analyzer System per site. For each run, each sample was run in duplicate each day for a total of 20 days for a total of 40 results per site. The results were analyzed per site for within-run precision (repeatability) and for total precision (combined within-run and run-to-run). All three POC sites produced similar results. Representative results from one site are summarized in the tables below:

Analyte	Mean	Within-Run SD	Total SD
Hct (%)	61	0.7	0.8
	38	0.3	0.3
	27	0.5	0.5

Analyte	Mean	Within-Run SD	Total SD
sO_2 (%)	48	0.6	0.7
	78	0.3	0.4
	91	0.5	0.4

Analyte	Mean	Within-Run SD	Within-Run %CV	Total SD	Total %CV
tHb (g/dL)	19.7	0.2	0.9	0.2	1.1
	12.9	0.1	1.0	0.2	1.5
	6.3	0.1	1.6	0.1	2.1

Analyte	Mean	Within-Run SD	Within-Run %CV	Total SD	Total %CV
O_2Hb (%)	20.9	0.3	1.5	0.4	2.0
	47.3	0.2	0.3	0.4	0.9
	80.2	0.1	0.1	0.2	0.3

Analyte	Mean	Within-Run SD	Within-Run %CV	Total SD	Total %CV
COHb (%)	29.1	0.2	0.7	0.2	0.9
	21.7	0.1	0.7	0.3	1.2
	6.5	0.1	2.0	0.1	2.2

Analyte	Mean	Within-Run SD	Within-Run %CV	Total SD	Total %CV
MetHb (%)	27.7	0.1	0.4	0.1	0.4
	18.4	0.2	1.1	0.2	1.2
	5.8	0.1	2.2	0.1	2.3

Analyte	Mean	Within-Run SD	Within-Run %CV	Total SD	Total %CV
HHb (%)	22.7	0.1	0.5	0.1	0.6
	13.2	0.2	1.2	0.2	1.2
	7.9	0.1	1.5	0.1	1.7

2. Linearity:

   Previously established in k180186.

3. Analytical Specificity/Interference:

   Previously established in k180186.

4. Assay Reportable Range:

   Previously established in k180186.

Analyte	Measurement Range
Hct (%)	12 – 70
sO_2 (%)	30 – 100
tHb (g/dL)	5.0 – 25.0
O_2 Hb (%)	1.8 – 100
COHb (%)	0.3 – 60
MetHb (%)	0.3 – 60
HHb (%)	0.4 – 40

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

   Previously established in k180186.

6. Detection Limit:

   Previously established in k180186.

7. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:
   The accuracy performance of the Stat Profile® Prime Plus Analyzer System for Hct, sO_2, tHb, O_2Hb, COHb, MetHb, and HHb was established with a method comparison study by assessing agreement with the predicate device. The method comparison studies were conducted at three POC sites: a Cardiothoracic Intensive Care Unit, an Emergency Department, and a Respiratory Therapy Lab. Samples of lithium heparinized arterial and venous whole blood were analyzed in singlicate using three Stat Profile® Prime Plus analyzers (one at each site). Across all sites, specimen handling and analysis was performed by 65 POC operators over a period of 20 testing days. In order to cover the claimed measuring range for each analyte, less than 10% of samples for each analyte were altered. The results obtained by POC operators were compared to the results obtained by trained healthcare professionals from the same whole blood specimens testing with the predicate device. Each of the three sites produced similar method comparison data. Linear regression analysis for venous and arterial whole blood results with all POC sites combined is presented in the table below.

Analyte	N	Range	Slope	Intercept	r
Hct (%)	417	18 - 69	0.999	0.132	0.993
sO_2 (%)	398	30 - 100	1.008	-0.966	0.998
tHb (g/dL)	416	5 - 24.2	1.004	-0.006	0.992
O_2Hb (%)	422	7.1 - 98.4	1.007	-0.864	0.998
COHb (%)	425	0.3 - 50.5	1.002	-0.001	0.999
MetHb (%)	437	0.3 - 56.7	1.004	0.001	0.999
HHb (%)	322	0.4 – 39.7	1.012	0.088	0.996

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 Hct, sO_2, tHb, O_2Hb, COHb, MetHb, and HHb on the Stat Profile® Prime Plus Analyzer System are cited from the literature:

Analyte	Reference ranges
Hct	Male: 39 – 49% Female: 35 – 45%
sO_2 (Arterial Whole Blood)	95 – 98%
tHb	Male: 14.0 – 17.8 g/dL Female: 12.0 – 15.6 g/dL
O_2Hb (Arterial Whole Blood)	94 – 97%
COHb (Nonsmoking)	0.0 – 1.5%
MetHb	0.0 – 1.5%
HHb	0.0 – 5.0%

References:

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Kost, G.T., "The Significance of Ionized Calcium in Cardiac and Critical Care," Arch. Pathol. Lab Med. Vol. 117: pp 890-896. 1993.

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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.