Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K191626

B Applicant

Nova Biomedical Corporation

C Proprietary and Established Names

Stat Profile Prime ES Comp Plus Analyzer System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
JFP	Class II	21 CFR 862.1145 – Calcium test system	CH - Clinical Chemistry
CHL	Class II	21 CFR 862.1120 - Blood Gases (PCO2, PO2) And Blood Ph Test System	CH - Clinical Chemistry
CFA	Class I, reserved	21 CFR 862.1495 - Magnesium test system	CH - Clinical Chemistry
GKF	Class II	21 CFR 864.6400 - Hematocrit measuring device	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Ionized calcium (iCa), Ionized magnesium (iMg), pH and Hematocrit (Hct)

C Type of Test:

iCa, iMg and pH – Quantitative, ion selective sensor
Hct – quantitative, impedance sensor

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Stat Profile Prime ES Comp Plus Analyzer System is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings for the quantitative determination of pH, Hematocrit, Ionized Calcium and Ionized Magnesium in heparinized venous whole blood, and pH, Ionized Calcium and Ionized Magnesium in plasma and serum.

Ionized Calcium (iCa) measurements are used in the diagnosis and treatment of parathyroid disease, a variety ofbone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Ionized Magnesium (iMg) measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low levels of magnesium) and hypermagnesemia (abnormally high levels of magnesium).

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

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

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Not for Point-of-care use

D Special Instrument Requirements:

Stat Profile Prime ES Comp Plus Analyzer System

IV Device/System Characteristics:

A Device Description:

The Stat Profile Prime ES Comp Plus Analyzer is a blood electrolyte analyzer. It consists of the analyzer, sensor cartridges, and thermal paper for an onboard printer. Optionally, it provides for reading of barcode labels (such as operator badges and data sheets). The Stat Profile Prime ES Comp Plus Analyzer has an enhanced test menu and multiple quality control options. External Control Solutions (ampules) shall be offered, as well as an on-board Quality Management System (QMS), an electronic monitoring approach that insures the analyzer is working properly.

The Stat Profile Prime ES Comp Plus Analyzer can accommodate either of two sensor cards in the sensor card housing. The analyzer will determine the test configuration of the system by detecting which sensor card is installed. The two options for the sensor card are:

- Sensor Card 1 (Basic Electrolyte Panel plus Hct) shall enable and report the following listed analytes: Hct, Na, K, Cl
- Sensor Card 2 (Full Electrolyte Panel plus pH & Hct) shall enable and report the following listed analytes: pH, Hct, Na, K, Cl, iCa, iMg

The Stat Profile Prime ES Comp Plus Analyzer is microprocessor-based and incorporates ion selective electrode technology to measure pH, ionized calcium, ionized magnesium.

The Prime ES Comp Plus can be configured with an optional sample tray, which allows the user to run up to 10 consecutive samples. Tray samples may be any combination of Serum/Plasma or control solutions. Whole Blood samples may only be run in STAT Mode (not tray mode). Calibration standards are provided in sealed pouches within a calibrator pack. Liquid quality control materials are available as external ampules. Sampling and calibration are fully automated. The Stat Profile Prime ES Comp Plus Analyzer accepts lithium heparinized whole blood sample from syringes, open tubes, and small cups. The minimum sample sizes for analysis is 100 μL.

B Principle of Operation:

iCa, iMg, pH
The parameters are measured by ion-selective electrodes (ISE) selectively measures the activity of ionic species (iCa, iMg, or hydrogen ion). When the ISE is contacted with a sample, potential is developed. The potential is proportional to the logarithm of the ionic activity and is measured versus a reference electrode, as described by the Nernst equation.

Hct
Hematocrit results are obtained by an impedance sensor measuring electrical resistance of the blood sample. Two standard solutions are used to calibrate the hematocrit sensor and to obtain the slope. The analyzer then measures the electrical resistance of the blood sample to obtain the hematocrit value.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Nova Stat Profile pHOx Ultra Analyzer System

B Predicate 510(k) Number(s):
K110648

C Comparison with Predicate(s):

Device & Predicate Device(s):	K191626	K110648
Device Trade Name	Stat Profile Prime ES Comp Plus Analyzer System	Nova Stat Profile pHOx Ultra Analyzer System
General Device Characteristic Similarities		
Intended Use/Indications For Use	Quantitative measurement of iCa, iMg, pH, and Hct in heparinized venous whole blood, and pH, ionized calcium and ionized magnesium in plasma and serum.	Same
Measurement Principle	*iCa, iMg. pH*: Ion-selective sensor *Hct*: Impedance Sensor	Same
Measurement Range - iMg	0.1-1.5 mmol/L	Same
Measurement Range - pH	6.500-8.000	Same
Measurement Range – Hct	12-70%	Same
General Device Characteristic Differences		
Measurement Range - iCa	0.20-2.70 mmol/L	0.10-2.70 mmol/L
Intended User	Central Laboratory	Central Laboratory and Point-of-Care
Sample Type	Lithium heparin whole blood, serum and lithium heparin plasma samples	Sodium or lithium heparinized whole blood, serum, or plasma samples

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Third Edition.
- CSLI EP06-A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.
- CLSI EP07-A3 Interference Testing in Clinical Chemistry; Approved Guideline - Third Edition.
- CLSI EP-17A Protocols fort Determination of Limits of Detection and Limits of Quantitation; Approved Guideline.
- EP25-A: Evaluation of In Vitro Diagnostic Reagents; Approved Guideline.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Within-Run Precision:
The study was performed following the CLSI EP05-A3 guideline. Within-Run and between-analyzer precision study was performed using two levels of quality control (QC) materials, whole blood, serum and plasma on three Stat Profile Prime ES Comp Plus analyzers. Each sample was tested in one run in replicates of 20 on each of the three analyzers. The results of one representative analyzer are summarized in the tables below:

Within-run precision using External Quality samples:

Parameter	n=20	External Control Level 1	External Control Level 2
iCa (mmol/L)	Mean SD CV%	1.15 0.004 0.3	1.89 0.02 1.0
iMg (mmol/L)	Mean SD CV%	0.47 0.01 1.2	1.09 0.01 1.0
pH	Mean SD	7.37 0.003	7.51 0.002
Hct (%)	Mean SD	51 0.04	65 0.8

Within-run precision using whole blood samples:

iCa (mmol/L) (n=20)			
Sample	Mean	SD	%CV
Sample 1	0.71	0.003	0.4
Sample 2	1.29	0.01	0.5
Sample 3	1.85	0.004	0.2

iMg (mmol/L) (n=20)			
Sample	Mean	SD	%CV
Sample 1	0.19	0.004	1.9
Sample 2	0.50	0.01	1.8
Sample 3	1.00	0.01	0.7

pH (n=20)		
Sample	Mean	SD
Sample 1	7.18	0.008
Sample 2	7.43	0.004
Sample 3	7.73	0.004

Hct (%) (n=20)		
Sample	Mean	SD
Sample 1	25	0.3
Sample 2	48	0.3
Sample 3	64	0.6

Within-run precision using lithium heparin plasma samples

iCa (mmol/L) (n=20)			
Sample	Mean	SD	%CV
Sample 1	0.81	0.01	0.7
Sample 2	1.22	0.002	0.2
Sample 3	1.53	0.003	0.2

iMg (mmol/L) (n=20)			
Sample	Mean	SD	%CV
Sample 1	0.19	0.004	1.9
Sample 2	0.52	0.01	1.1
Sample 3	1.29	0.004	0.3

pH (n=20)		
Sample	Mean	SD
Sample 1	7.15	0.010
Sample 2	7.45	0.004
Sample 3	7.76	0.005

Within-run precision using serum samples

iCa (mmol/L) (n=20)			
Sample	Mean	SD	%CV
Sample 1	0.87	0.01	1.1
Sample 2	1.21	0.002	0.1
Sample 3	1.57	0.003	0.2

iMg (mmol/L) (n=20)			
Sample	Mean	SD	%CV
Sample 1	0.20	0.01	2.6
Sample 2	0.46	0.01	1.5
Sample 3	1.31	0.01	1.0

pH (n=20)		
Sample	Mean	SD
Sample 1	7.17	0.009
Sample 2	7.43	0.006
Sample 3	7.78	0.015

Run-to-run precision:

Run-to-run precision was assessed by analyzing QC samples, each sample was tested in duplicate per run, 2 runs per day, 3 analyzers performed over 20 days. The summary results for the four analyte test systems are shown below:

Run-to-run precision using External QC samples:

iCa (mmol/L)						
Sample	Pooled mean	N	Within run		Total imprecision	
			SD	%CV	SD	%CV
QC level 1	1.15	240	0.01	0.9	0.01	0.9
QC level 2	1.88	240	0.01	0.5	0.01	0.5

iMg (mmol/L)						
Sample	Pooled mean	N	Within run		Total imprecision	
			SD	%CV	SD	%CV
QC level 1	0.47	240	0.007	1.4	0.01	2.1
QC level 2	1.09	240	0.01	0.9	0.04	3.7

pH				
Sample	Pooled mean	N	Within run SD	Total imprecision SD
QC level 1	7.374	240	0.002	0.003
QC level 2	7.550	240	0.002	0.002

Hct (%)				
Sample	Pooled mean	N	Within run SD	Total imprecision SD
QC level 1	51	240	0.3	0.4
QC level 2	66	240	0.5	0.6

Run-to-run precision using whole blood, plasma, and serum samples:

To assess run-to-run precision whole blood, plasma and serum samples, triplicate analysis was performed using each of the three sample matrices in ten separate runs on three analyzers for a total of 30 data sets. The systems were recalibrated before each triplicate run. Samples were analyzed on three analyzers. The results from one representative analyzer are summarized in the table below:

Lithium heparin whole blood:

Parameter	N=30	Sample 1	Sample 2	Sample 3
iCa (mmol/L)	Mean	0.83	1.22	1.6
	SD	0.003	0.003	0.02
	CV%	0.3	0.2	1.3
iMg (mmol/L)	Mean	0.21	0.45	1.46
	SD	0.005	0.003	0.02
	CV%	2.3	0.7	1.0
pH	Mean	7.12	7.37	7.64
	SD	0.016	0.003	0.015
Hct (%)	Mean	17	44	63
	SD	1.1	0.4	0.7

Lithium heparin plasma

Parameter	N=30	Sample 1	Sample 2	Sample 3
iCa (mmol/L)	Mean	0.87	1.19	1.65
	SD	0.01	0.00	0.01
	CV%	0.8	0.4	0.6
iMg (mmol/L)	Mean	0.23	0.50	1.27
	SD	0.01	0.01	0.01
	CV%	2.3	1.5	1.0
pH	Mean	7.19	7.48	7.77
	SD	0.011	0.005	0.010

Serum

Parameter	N=30	Sample 1	Sample 2	Sample 3
iCa (mmol/L)	Mean	0.86	1.10	1.61
	SD	0.01	0.01	0.004
	CV%	1.2	0.8	0.2
iMg (mmol/L)	Mean	0.22	0.48	1.27
	SD	0.002	0.002	0.01
	CV%	0.9	0.4	1.0
pH	Mean	7.14	7.40	7.67
	SD	0.013	0.007	0.015

2. Linearity:

The linearity studies were performed following the CLSI EP6-A guideline to establish the analytical measurement range for each test system. The studies were performed on three analyzers using lithium heparinized venous whole blood, lithium heparin plasma and serum for pH, iCa, and iMg. Only lithium heparin whole blood was tested for Hct. Low and high concentration pools were mixed to create 9-11 serial dilution samples that were tested in triplicate. The results from each candidate analyzer for each parameter were compared to the expected values. All three analyzers yielded similar results. The results of the least squares linear regression analysis from one representative analyzer are summarized below:

Lithium heparin whole blood:

Analyte	Claimed Measuring Range	Sample Range Tested	Slope	Intercept	r
iCa (mmol/L)	0.1-2.7	0.07-2.84	1.0068	-0.0241	0.9997
iMg (mmol/L)	0.1-1.5	0.09-1.66	1.0080	0.0004	0.9996
pH	6.5-8.0	6.42-8.23	1.0031	-0.0231	0.9997
Hct (%)	12-70	9-72	0.9873	0.8159	0.9986

Lithium heparin plasma:

Analyte	Claimed Measuring Range	Sample Range Tested	Slope	Intercept	r
iCa (mmol/L)	0.1-2.7	0.08-2.81	1.0079	-0.0064	0.9997
iMg (mmol/L)	0.1-1.5	0.09-1.73	1.0089	0.0103	0.9988
pH	6.5-8.0	6.38-8.19	0.9898	0.0734	0.9996

Serum:

Analyte	Claimed Measuring Range	Sample Range Tested	Slope	Intercept	r
iCa (mmol/L)	0.1-2.7	0.08-2.90	0.9941	0.0252	0.9998
iMg (mmol/L)	0.1-1.5	0.09-1.62	1.0169	-0.0010	0.9993
pH	6.5-8.0	6.43-8.10	0.9878	0.0923	0.9997

The linear regression results support the claimed measuring ranges, as summarized in the tables above.

3. Analytical Specificity/Interference:

Interference studies were performed according to CLSI EP07-A3 guideline. The sponsor collected serum sample and plasma from donors. Samples were divided to create two separate pools one for control and the other for test samples. The potential interferents were tested at two analyte concentrations. If interference was identified, then a dose response was performed to determine the lowest concentration where the interfering substance may alter the results. For all analytes, the sponsor defined interference as > ± 10% bias from the test concentration when compared to the control sample.

The results of the interference study for whole blood, serum, and plasma samples are summarized below:

iCa:

Interferent	Highest concentration tested that did not cause significant interference
Acetoacetate	2 mmol/L
Acetylsalicyclic acid	3.62 mmol/L
Ammonium chloride	107 µmol/L
Ascorbic acid	50 mg/dL
Benzalkonium chloride	10 mg/L
Bilirubin	342 µmol/L
Dobutamine	2 mg/dL
Hemoglobin	2 g/L
Ibuprofen	2.4 mmol/L
Intralipid	4000 mg/dL
Lithium lactate	6.6 mmol/L
Magnesium chloride	15 mmol/L
Potassium chloride	5 mmol/L
Salicylic acid	4.34 mmol/L
Sodium bromide	37.5 mmol/L
Sodium chloride	10 mmol/L
Sodium iodide	2.99 mmol/L
Sodium perchlorate	1 mmol/L
Sodium thiocyanate	6.8 mmol/L
Zinc chloride	1.3 mg/dL

iMg:

Interferent	Highest concentration tested that did not cause significant interference
Acetoacetate	2 mmol/L
Acetylsalicyclic acid	3.62 mmol/L
Ammonium chloride	107 µmol/L
Ascorbic acid	50 mg/dL
Benzalkonium chloride	10 mg/L
Bilirubin	342 µmol/L
Calcium chloride	2 mmol/L
Dobutamine	2 mg/dL
Hemoglobin	2 g/L
Ibuprofen	2.4 mmol/L
Intralipid	4000 mg/dL
Lithium lactate	6.6 mmol/L
Potassium chloride	5 mmol/L
Sodium bromide	37.5 mmol/L
Sodium chloride	10 mmol/L
Sodium iodide	2.99 mmol/L
Sodium perchlorate	1 mmol/L

Interferent	Highest concentration tested that did not cause significant interference
Sodium thiocyanate	6.8 mmol/L
Zinc chloride	1.3 mg/dL

pH

Interferent	Highest concentration tested that did not cause significant interference
Acetaminophen	20 mg/dL
Benzalkonium chloride	10 mg/L
Bilirubin	342 µmol/L
Calcium chloride	2 mmol/L
Dextran	60 g/L
Dobutamine	2 mg/dL
Ethanol	86.8 mmol/L
Fluorescein	0.4 mg/mL
Halothane	759 µmol/L
Hemoglobin	2 g/L
Hydroxybutyrate	2 mmol/L
Hydroxyurea	0.8 mg/dL
Intralipid	4000 mg/dL
Lithium chloride	3.2 mmol/L
Ofloxacin	48.6 mmol/L
Potassium chloride	5 mmol/L
Sodium bromide	37.5 mmol/L
Sodium chloride	10 mmol/L
Sodium heparin	100 iU/mL
Sodium iodide	2.99 mmol/L

Hct (lithium heparin whole blood):

Interferent	Highest concentration tested that did not cause significant interference
Acetylcysteine	10.2 mmol/L
Albumin	15 g/dL
Bilirubin conjugate	342 µmol/L
Hemoglobin	2 g/L
Hemolysis	10%
Hydroxocobalamin	0.6 g/L
Intralipid	4000 mg/dL
Sodium heparin	100 iU/mL
Triglycerides	2101 mg/dL
WBC	40.1 x 10^3/uL

Substances that had a bias that exceeded the manufacturer's specifications were tested in dose response studies according to CLSI guideline EP07-A3. The results are described below.

Parameter	Interfering Substance	Concentration at which interference may occur
iCa	Magnesium chloride	>3.75 mmol/L
iMg	Dobutamine	>0.5 mg/dL
	Perchlorate	>0.06 mmol/L
	Thiocyanate	>0.4 mmol/L
	Zinc chloride	>0.16 mg/dL
Hematocrit (Blood only)	Albumin	>3.8 g/dL
	Hemolysis	>5%
	Triglycerides	>402 mg/dL

The sponsor has listed the above interferents in the labeling.

4. Assay Reportable Range:

Analyte	Claimed Measuring Range
iCa	0.1 - 2.7 mmol/L
iMg	0.1 - 1.5 mmol/L
pH	6.5 - 8.0
Hct	12 - 70 %

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

The iCa reagent is traceable to NIST SRM 2193.

The iMg reagent is traceable to NIST SRM 929a.

pH standards and reagents used for Nova's products are traceable to National Institute of Standards and Technology (NIST) SRMs 2183, 2184, 2181 and 2182. The validation is accomplished by using a hydrogen ion selective glass membrane.

The Hct measurements were performed by the microhematocrit method defined in CLSI H07-A3 which calls for whole blood to be centrifuged and the percentage of packed red cells calculated. Results from the reference method were compared to measurements from a Nova analyzer.

6. Detection Limit:

The limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) were determined for iCa and iMg according to CLSI EP17-A2 guideline. Two reagent lots were used for each study.

For LoB studies, blank samples were run five times on two analyzers with different lots. Four different blank samples were run over three days, giving a total of 60 replicates per lot. The LoB was calculated by sorting the samples from low to high and averaging the 57th and 58th sample using the typical Type I error risk of α=0.05. The greater LoB of the two reagent lots was reported as the LoB.

For LoD studies, samples with low levels of iCa and iMg were prepared and run four times on two analyzers with different lots. Five different low level samples were run over three days, giving a total of 60 replicates per lot. The results were pooled to calculate the total standard deviation (SDL) per calibrator lot. The LoD was calculated using the equation: LoD = LoB + C_pSD_L. The greater LoD of the two lots was reported as the LoD.

For LoQ studies, samples with low levels of iCa and iMg were prepared and run three times on two analyzers with different lots. Each low level sample was measured on the pHOx Ultra for a reference value. Four different low-level samples were run over three days, giving a total of 36 replicates per lot. The mean, SD, and bias relative to the reference values was calculated for each sample per calibrator lot. These values were used to calculate TE using the equation TE = |Bias| + 2s for each sample and expressed as concentrations relative to the respective reference value for each sample. The LoQ was defined as the lowest concentration at which measured total error is less than the pre-defined total error of $\leq$ 0.05 mmol/L for iCa and $\leq$0.10 mmol/L for iMg.

The overall results of LoB, LoD, and LoQ for each matrix are summarized below:

Lithium heparin whole blood			
Analyte	LoB	LoD	LoQ
iCa (mmol/L)	0.04	0.05	0.05
iMg (mmol/L)	0.01	0.01	0.04

Lithium heparin plasma			
Analyte	LoB	LoD	LoQ
iCa (mmol/L)	0.04	0.04	0.07
iMg (mmol/L)	0.02	0.02	0.04

Serum			
Analyte	LoB	LoD	LoQ
iCa (mmol/L)	0.04	0.05	0.07
iMg (mmol/L)	0.01	0.01	0.04

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A method comparison study was performed to compare results from one Stat Profile Prime ES Comp Plus to results from two Stat Profile pHOx Ultra analyzers (predicate) for whole blood, plasm, and serum samples. For each analyte, the singlet result from the test analyzer was compared to the average of the results from the two comparative methods. A minimum of 150 whole blood specimens, 100 plasma specimens, and 100 serum specimens were used.

In addition, a limited number of contrived samples were used to cover the hard-to-find concentrations of the claimed ranges.
The linear regression analyses for the four analytes are summarized below:

Lithium heparin whole blood:

Analyte	Slope	Intercept	r^2	N	Range tested
iCa (mmol/L)	1.0065	-0.0229	0.9957	191	0.27-2.62
iMg (mmol/L)	1.0040	-0.0096	0.9815	185*	0.26-1.43
pH	1.0040	-0.0259	0.9884	188*	6.52-7.97
Hct (%)	1.0023	0.1377	0.9856	183*	15-66

*N is smaller due to error, calibration status, or insufficient sample volume to complete analysis.

Lithium heparin plasma:

Analyte	Slope	Intercept	r^2	N	Range tested
iCa (mmol/L)	1.0009	-0.0002	0.9988	121	0.16-2.68
iMg(mmol/L)	0.9902	0.0154	0.9838	121	0.14-1.36
pH	0.9973	0.0225	0.9965	119*	6.59-7.98

*N is smaller due to error, calibration status, or insufficient sample volume to complete analysis.

Serum:

Analyte	Slope	Intercept	r^2	N	Range tested
iCa (mmol/L)	1.0029	0.0081	0.9987	115	0.19-2.64
iMg (mmol/L)	1.0022	0.0053	0.9868	115	0.14-1.44
pH	1.0030	-0.0236	0.9982	115	6.69-7.99

2. Matrix Comparison:

The performance of iCa, iMg and pH with lithium heparin venous whole blood, lithium heparin plasma and serum were evaluated per the studies described in sections VII.A 1 to 5 and VII.B.1. Please refer to the performance studies above.

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 range for iMg, iCa, pH, and /Hct are cited from literature:
iCa[1]: 4.36-5.20 mg/dL
iMg[2]: 1.09-1.45 mg/dL
pH[3]: 7.350-7.450
Hct[3]: Males: 39-49%, Females: 35-45%

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

[2]This is an average reference range that was determined from reference ranges established in a dozen or so reporting institutions that have been working with Nova analyzers. The extremes of the reference ranges in these institutions were 0.43 - 0.57 to 0.46 - 0.62 with most being 0.45 - 0.60 mmol/L.

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

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.